H. R. 5951

To improve the health of Americans and reduce health care costs by reorienting the Nation's health care system toward prevention, wellness, and self care.

IN THE HOUSE OF REPRESENTATIVES

July 27, 2006

Mr. Udall of New Mexico (for himself, Ms. Woolsey, and Mr. Moran of Virginia) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Education and the Workforce, and Government Reform, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To improve the health of Americans and reduce health care costs by reorienting the Nation's health care system toward prevention, wellness, and self care.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.
- 4 (a) Short Title.—This Act may be cited as the
- 5 "Healthy Lifestyles and Prevention America Act" or the
- 6 "HeLP America Act".

1 (b) Table of Contents of

2 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings.

TITLE I—HEALTHIER KIDS AND SCHOOLS

- Sec. 101. Fresh Fruit and Vegetable Program.
- Sec. 102. Food of minimal nutritional value.
- Sec. 103. School nutrition environment enhancement grants.

TITLE II—HEALTHIER COMMUNITIES AND WORKPLACES

Subtitle A—Incentives for a Healthy Workforce

- Sec. 201. Short title.
- Sec. 202. Tax credit to employers for costs of implementing wellness programs.
- Sec. 203. Income exclusion for employer-provided off-premises health club services.
- Sec. 204. CDC and employer-based wellness programs.

Subtitle B—Healthy Communities

- Sec. 211. Healthy community grants.
- Sec. 212. Preventive medicine and public health training grant program.

Subtitle C—Family Smoking Prevention and Control

- Sec. 221. Short title.
- Sec. 222. Findings.
- Sec. 223. Purpose.
- Sec. 224. Scope and effect.
- Sec. 225. Severability.

PART I—AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION

- Sec. 231. Amendment of Federal Food, Drug, and Cosmetic Act.
- Sec. 232. Interim final rule.
- Sec. 233. Conforming and other amendments to general provisions.

PART II—TOBACCO PRODUCT WARNINGS; CONSTITUENT AND SMOKE CCONSTITUENT DISCLOSURE

- Sec. 235. Cigarette label and advertising warnings.
- Sec. 236. Authority to revise cigarette WARNING label statements.
- Sec. 237. State regulation of cigarette advertising and promotion.
- Sec. 238. Smokeless tobacco labels and advertising warnings.
- Sec. 239. Authority to revise smokeless tobacco product WARNING label statements.
- Sec. 240. Tar, nicotine, and other smoke constituent disclosure to the public.

PART III—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

- Sec. 241. Labeling, recordkeeping, records inspection.
- Sec. 242. Study and report.

TITLE III—RESPONSIBLE MARKETING AND CONSUMER AWARENESS

Subtitle A—General Provisions

- Sec. 301. Nutrition labeling of restaurant foods.
- Sec. 302. Rulemaking authority for advertising to children.
- Sec. 303. Food advertising in schools.
- Sec. 304. Disallowance of deductions for advertising and marketing expenses relating to Tobacco product use.
- Sec. 305. Federal-State Tobacco counter-advertising programs.

Subtitle B—Penalties for Failure to Reduce Teen Smoking

- Sec. 311. Child cigarette use surveys.
- Sec. 312. Cigarette use reduction goal and noncompliance.
- Sec. 313. Enforcement.

TITLE IV—REIMBURSEMENT AND COVERAGE OF PREVENTIVE SERVICES

- Sec. 401. Coverage of substance use (other than tobacco), diet, exercise, injury prevention, and dental health counseling.
- Sec. 402. Encouragement of cessation of tobacco use.
- Sec. 403. Recognition of school-based health centers as model for delivery of primary care for children under Medicaid and the State Children's Health Insurance Program.
- Sec. 404. Preventive health care demonstration program.
- Sec. 405. Preventive health services for women.

TITLE V—HELP (HEALTHY LIFESTYLES AND PREVENTION) AMERICA TRUST FUND

Sec. 501. HeLP (Healthy Lifestyles and Prevention) America Trust Fund.

TITLE VI—RESEARCH

Sec. 601. Expansion of research regarding obesity.

1 SEC. 2. FINDINGS.

- 2 Congress makes the following findings:
- 3 (1) Health care costs in the United States are
- 4 rising rapidly. Per capita health spending in the
- 5 United States is 56 percent higher than the median
- 6 country that is a member of the Organization for
- 7 Economic Cooperation and Development.
- 8 (2) According to the Centers for Medicare and
- 9 Medicaid Services, total health care spending in the

- United States in 2004 was \$1,800,000,000,000 and is expected to rise to \$3,600,000,000,000 by 2014.

 Furthermore, chronic disease accounts for approximately 75 percent of health care costs annually.
- 5 (3) The United States spends less than 5 per-6 cent of annual health care expenditures on preven-7 tion
 - (4) Reducing and preventing the incidence of chronic disease is one means by which to reduce health care costs in the United States.
 - (5) More than 1,700,000 Americans die of a chronic disease each year, accounting for nearly 70 percent of all deaths in the United States.
 - (6) The economic impact of chronic disease can be seen in the annual costs associated with cardio-vascular disease and stroke (\$352,000,000,000), obesity (\$117,000,000,000), cancer (\$171,600,000,000), and diabetes (\$132,000,000,000).
 - (7) Obesity related health conditions cost employers nearly \$13,000,000,000 in health care and other indirect costs.
- 23 (8) Health promotion investments by employers 24 on average yield a return of \$3 for every \$1 invested 25 in a program.

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- 1 (9) Being overweight or obese increase the risk 2 of diabetes, heart disease, stroke, several types of 3 cancer and other health problems.
 - (10) An estimated 65 percent of adults and 15 percent of children and adolescents in the United States are overweight or obese.
 - (11) The rates of obesity have doubled in children and tripled in teens since the 1980's.
 - (12) Almost 40 percent of Americans are sedentary. More than \(\frac{1}{3}\) of young people in grades 9 through 12 do not regularly engage in vigorous-intensity physical activity.
 - (13) Only 1 in 5 young people eat the recommended 5 daily servings of fruits and vegetables.
 - (14) Food and beverage advertisers collectively spend \$10,000,000,000 to \$12,000,000,000 a year to reach children and youth.
 - (15) Between 1977 and 1995, trips made by walking declined by 40 percent for adults while driving trips increased to almost 90 percent of the total.
 - (16) Virtually all-new users of tobacco products are under the minimum legal age to purchase such products. Every day in America, more than 4,000 kids try their first cigarette. Another 2,000 children

25 become new daily smokers.

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1	(17) In 2002, nearly a quarter of American
2	adults, 46,000,000 people, smoked cigarettes, includ-
3	ing almost 40 percent of college-aged students.
4	(18) Research consistently shows that smoking
5	cessation services offered as a combination of to-
6	bacco medication therapy and counseling can be one
7	of the most cost-effective health interventions and
8	can reduce smoking-related health care costs.
9	TITLE I—HEALTHIER KIDS AND
10	SCHOOLS
11	SEC. 101. FRESH FRUIT AND VEGETABLE PROGRAM.
12	(a) Additional Funding for Fresh Fruit and
13	VEGETABLE PROGRAM.—Section 18(g)(6)(B) of the Rich-
14	ard B. Russell National School Lunch Act (42 U.S.C.
15	1769(g)(6)(B)) is amended—
16	(1) by redesignating clause (ii) as clause (iv);
17	and
18	(2) by inserting after clause (i) the following:
19	"(ii) Additional mandatory fund-
20	ING.—Out of any funds in the Treasury
21	not otherwise appropriated, the Secretary
22	of the Treasury shall transfer to the Sec-
23	retary of Agriculture to carry out and ex-
24	pand the program under this subsection, to
25	remain available until expended—

1	(I) on October 1, 2006,
2	\$1,000,000,000; and
3	"(II) on October 1, 2007, and on
4	each October 1 thereafter, the amount
5	made available for the previous fiscal
6	year, as adjusted under clause (iii).
7	"(iii) Adjustment.—On October 1,
8	2007, and on each October 1 thereafter of
9	a fiscal year the amount made available
10	under subclause (II) of clause (ii) shall be
11	calculated by adjusting the amount made
12	available for the previous fiscal year to re-
13	flect changes in the Consumer Price Index
14	of the Bureau of Labor Statistics for fresh
15	fruits and vegetables, with the adjust-
16	ment—
17	"(I) rounded down to the nearest
18	dollar increment; and
19	"(II) based on the unrounded
20	amounts for the preceding 12-month
21	period.".
22	(b) Healthy Cooking Pilot Program.—Section
23	18(g) of the Richard B. Russell National School Lunch
24	Act (42 U.S.C. 1769(g)) is amended—

1	(1) by redesignating paragraphs (4), (5), and
2	(6) as paragraphs (5), (6), and (7), respectively; and
3	(2) by inserting after paragraph (3) the fol-
4	lowing:
5	"(4) Healthy cooking pilot program.—
6	"(A) In general.—As part of the pro-
7	gram conducted under this subsection, the Sec-
8	retary shall carry out a pilot program under
9	which the Secretary shall make competitive
10	grants to selected elementary and secondary
11	schools to teach children—
12	"(i) how to eat a nutritious diet;
13	"(ii) how to select foods to make a
14	healthy meal; and
15	"(iii) how to prepare healthy meals.
16	"(B) Selection of schools.—In select-
17	ing schools to participate in the pilot program,
18	the Secretary shall ensure that—
19	"(i) only schools participating in the
20	fruit and vegetable program under this
21	subsection are eligible to receive funds
22	under this paragraph;
23	"(ii) to the maximum extent prac-
24	ticable, at least 75 percent of schools se-
25	lected are schools in which at least 50 per-

1	cent of the students enrolled are eligible
2	for free or reduced price meals under this
3	Act; and
4	"(iii) there is appropriate representa-
5	tion, as determined by the Secretary, of—
6	"(I) rural, urban, and suburban
7	schools; and
8	"(II) elementary, middle, and
9	secondary schools.
10	"(C) Priority consideration.—In
11	awarding competitive grants under this para-
12	graph, the Secretary shall give priority consid-
13	eration to schools that submit an application
14	that includes the participation of the parents or
15	families of the children enrolled in the school.".
16	SEC. 102. FOOD OF MINIMAL NUTRITIONAL VALUE.
17	Section 10 of the Child Nutrition Act of 1966 (42
18	U.S.C. 1779) is amended—
19	(1) by striking the section heading and all that
20	follows through "(a) The Secretary" and inserting
21	the following:
22	"SEC. 10. REGULATIONS.
23	"(a) In General.—The Secretary"; and
24	(2) by striking subsections (b) and (c) and in-
25	serting the following:

1	"(b) Food of Minimal Nutritional Value.—
2	"(1) Proposed regulations.—
3	"(A) In General.—Not later than 180
4	days after the date of enactment of this para-
5	graph, the Secretary shall promulgate proposed
6	regulations to revise the definition of 'food of
7	minimal nutritional value' that is used to carry
8	out this Act and the Richard B. Russell Na-
9	tional School Lunch Act (42 U.S.C. 1751 et
10	seq.).
11	"(B) Application.—The revised defini-
12	tion of 'food of minimal nutritional value' shall
13	apply to all foods sold—
14	"(i) outside the school meal programs;
15	"(ii) on the school campus; and
16	"(iii) at any time during the school
17	day.
18	"(C) REQUIREMENTS.—In revising the
19	definition, the Secretary shall consider—
20	"(i) both the positive and negative
21	contributions of nutrients, ingredients, and
22	foods (including calories, portion size, satu-
23	rated fat, trans fat, sodium, and added
24	sugars) to the diets of children;

1	"(ii) evidence concerning the relation-
2	ship between consumption of certain nutri-
3	ents, ingredients, and foods to both pre-
4	venting and promoting the development of
5	overweight, obesity, and other chronic ill-
6	nesses;
7	"(iii) recommendations made by au-
8	thoritative scientific organizations con-
9	cerning appropriate nutritional standards
10	for foods sold outside of the reimbursable
11	meal programs in schools; and
12	"(iv) special exemptions for school-
13	sponsored fundraisers (other than fund-
14	raising through vending machines, school
15	stores, snack bars, a la carte sales, and
16	any other exclusions determined by the
17	Secretary), if the fundraisers are approved
18	by the school and are infrequent within the
19	school.
20	"(2) Implementation.—
21	"(A) Effective date.—
22	"(i) In general.—Except as pro-
23	vided in clause (ii), the proposed regula-
24	tions shall take effect at the beginning of

1	the school year following the date on which
2	the regulations are finalized.
3	"(ii) Exception.—If the regulations
4	are finalized on a date that is not more
5	than 60 days before the beginning of the
6	school year, the proposed regulations shall
7	take effect at the beginning of the fol-
8	lowing school year.
9	"(B) Failure to promulgate.—If, on
10	the date that is 1 year after the date of enact-
11	ment of this paragraph, the Secretary has not
12	promulgated final regulations, the proposed reg-
13	ulations shall be considered to be final regula-
14	tions.".
15	SEC. 103. SCHOOL NUTRITION ENVIRONMENT ENHANCE-
16	MENT GRANTS.
17	Section 18 of the Richard B. Russell National School
18	Lunch Act (42 U.S.C. 1769) is amended by adding at the
19	end the following:
20	"(1) HEALTHY SCHOOL NUTRITION ENVIRONMENT
21	INCENTIVE GRANTS.—
22	"(1) In general.—Following the publication
23	of the recommendations of the Institute of Medicine
24	study carried out using funds made available for
25	public health improvement and leadership under the

1	heading 'Centers for Disease Control and Preven-
2	tion' in the Department of Labor Appropriations
3	Act, 2005 (title I of division F of Public Law 108–
4	447; 118 Stat. 3124) regarding appropriate nutri-
5	tional standards for the availability, sale, content,
6	and consumption of food at school, with particular
7	attention given to foods offered in competition with
8	federally reimbursed meals and snacks, the Sec-
9	retary may carry out a grant program to—
10	"(A) provide schools with technical assist-
11	ance in implementing the recommendations of
12	the Institute of Medicine regarding appropriate
13	school nutrition standards; and
14	"(B) assess the impact of implementing
15	the recommendations on the health and well-
16	being of children enrolled in the schools.
17	"(2) Selection of schools.—In selecting
18	schools to receive incentive grants under this sub-
19	section, the Secretary shall—
20	"(A) ensure that not less than 75 percent
21	of schools selected to participate in the program
22	established under this subsection are schools in
23	which not less than 50 percent of the students
24	enrolled in each school are eligible for free or
25	reduced price meals under this Act;

1	"(B) ensure that, of the schools selected to
2	participate in the program, there is appropriate
3	representation of rural, urban, and suburbar
4	schools, as determined by the Secretary;
5	"(C) ensure that, of the schools selected to
6	participate in the program, there is appropriate
7	representation of elementary, middle, and sec-
8	ondary schools, as determined by the Secretary
9	"(D) ensure that schools selected to receive
10	a grant under this subsection meet the require-
11	ments of paragraph (3);
12	"(E) give priority to schools that develop
13	comprehensive plans that include the involve-
14	ment of a broad range of community stake-
15	holders in achieving healthy school nutrition en-
16	vironments; and
17	"(F) give priority to schools that develop
18	comprehensive plans that include a strategy for
19	maintaining healthy school nutrition environ-
20	ments in the years following the fiscal years for
21	which the schools receive grants under this sub-
22	section.
23	"(3) Requirements.—
24	"(A) CRITERIA FOR HEALTHY SCHOOL EN-
25	VIRONMENTS.—The Secretary shall establish

1	criteria, based upon the recommendations of the
2	Institute of Medicine described in paragraph
3	(1), under which schools may receive grants
4	under this section.
5	"(B) Plan.—To be eligible to receive a
6	grant under this subsection, a school shall—
7	"(i) submit to the Secretary a healthy
8	school nutrition environment plan that de-
9	scribes the actions the school will take to
10	meet the criteria established under sub-
11	paragraph (A); and
12	"(ii) take the actions described in the
13	plan.
14	"(4) Grants.—For each of fiscal years 2007
15	through 2011, the Secretary shall make a grant to
16	each school selected under paragraph (2).
17	"(5) Evaluations.—
18	"(A) In General.—The Secretary, acting
19	through the Administrator of the Food and Nu-
20	trition Service, shall conduct an evaluation of a
21	representative sample of schools that receive
22	grants under this subsection.
23	"(B) Content.—The evaluation shall
24	measure, at a minimum, the effects of a healthy
25	school nutrition environment on—

1	"(i) overweight children and obesity;
2	"(ii) dietary intake;
3	"(iii) nutrition education and behav-
4	ior;
5	"(iv) parental and student attitudes
6	and participation; and
7	"(v) related funding issues, including
8	the cost of maintaining a healthy school
9	nutrition environment.
10	"(C) Reports.—The Secretary shall sub-
11	mit to the Committee on Education and the
12	Workforce of the House of Representatives and
13	the Committee on Agriculture, Nutrition, and
14	Forestry of the Senate—
15	"(i) an interim report on the activities
16	of schools evaluated under this subsection;
17	and
18	"(ii) a final report on the activities of
19	schools evaluated under this subsection.
20	"(6) Authorization of appropriations.—
21	"(A) In general.—There are authorized
22	to be appropriated such sums as are necessary
23	to carry out this subsection for fiscal year 2007
24	and each subsequent fiscal year, to remain
25	available until expended.

1	"(B) EVALUATIONS.—The Secretary may
2	use not more than 10 percent of the total funds
3	made available for a fiscal year under subpara-
4	graph (A) to carry out paragraph (5).".
5	TITLE II—HEALTHIER COMMU-
6	NITIES AND WORKPLACES
7	Subtitle A—Incentives for a
8	Healthy Workforce
9	SEC. 201. SHORT TITLE.
10	This subtitle may be cited as the "Healthy Workforce
11	Act of 2006".
12	SEC. 202. TAX CREDIT TO EMPLOYERS FOR COSTS OF IM-
13	PLEMENTING WELLNESS PROGRAMS.
14	(a) In General.—Subpart D of part IV of sub-
15	chapter A of chapter 1 of the Internal Revenue Code of
16	1986 (relating to business related credits) is amended by
17	adding at the end the following:
18	"SEC. 45N. WELLNESS PROGRAM CREDIT.
19	"(a) Allowance of Credit.—
20	"(1) In general.—For purposes of section 38,
21	the wellness program credit determined under this
22	section for any taxable year is—
23	"(A) in the case of a small business em-
24	ployer, an amount equal to 50 percent of the
25	costs paid or incurred by the small business em-

ployer in connection with a qualified small business wellness program during the taxable year, and

- "(B) in the case of any other employer, an amount equal to 50 percent of the costs paid or incurred by the employer in connection with a qualified wellness program during the taxable year.
- 9 "(2) LIMITATION.—The amount of credit allowed under paragraph (1) for any taxable year shall not exceed the product of \$200 and the number of employees of the employer or small business employer, as the case may be.
- 14 "(b) QUALIFIED WELLNESS PROGRAM; QUALIFIED
 15 SMALL BUSINESS WELLNESS PROGRAM.—For purposes
 16 of this section—
- "(1) QUALIFIED WELLNESS PROGRAM.—The 17 18 term 'qualified wellness program' means a program 19 which consists of all of the wellness program compo-20 nents described in subsection (c) and which is cer-21 tified by the Secretary of Health and Human Serv-22 ices, in consultation with persons who have expertise 23 in employer health promotion and wellness pro-24 grams, as a qualified wellness program under this 25 section.

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1	"(2) Qualified small business wellness
2	PROGRAM.—The term 'qualified small business
3	wellness program' means a program which consists
4	of any 2 of the components described in subsection
5	(c) and which is certified by the Secretary of Health
6	and Human Services, in consultation with persons
7	who have expertise in employer health promotion
8	and wellness programs, as a qualified small business
9	wellness program under this section.
10	"(c) Wellness Program Components.—For pur-
11	poses of this section, the wellness program components de-
12	scribed in this subsection are the following:
13	"(1) Health awareness component.—A
14	health awareness component which provides for the
15	following:
16	"(A) HEALTH EDUCATION.—The dissemi-
17	nation of health information which addresses
18	the specific needs and health risks of employees.
19	"(B) HEALTH SCREENINGS.—The oppor-
20	tunity for periodic screenings for health prob-
21	lems and referrals for appropriate follow up
22	measures.
23	"(2) Behavioral Change Component.—A
24	behavioral change component which provides for al-
25	tering employee lifestyles to encourage healthy living

1	through counseling, seminars, on-line programs, or
2	self-help materials. Such component shall include
3	programs relating to—
4	"(A) smoking,
5	"(B) obesity,
6	"(C) stress management,
7	"(D) physical fitness,
8	"(E) nutrition,
9	"(F) substance abuse,
10	"(G) depression,
11	"(H) mental health promotion (including
12	anxiety), and
13	"(I) sleep (including sleep disorders and
14	the consequences of sleep deprivation).
15	"(3) Supportive environment compo-
16	NENT.—A supportive environment component which
17	includes the following:
18	"(A) On-site policies.—Policies and
19	services at the worksite which promote a
20	healthy lifestyle, including policies relating to—
21	"(i) smoking at the worksite,
22	"(ii) the nutrition of food available at
23	the worksite through cafeterias and vend-
24	ing options,

1	"(iii) minimizing stress in the work-
2	place,
3	"(iv) where applicable, accessible and
4	attractive stairs,
5	"(v) the encouragement of physical
6	activity during work hours, and
7	"(vi) the promotion of fatigue coun-
8	termeasures.
9	"(B) Participation incentives.—
10	"(i) In general.—Qualified incentive
11	benefits for each employee who participates
12	in the health screenings described in para-
13	graph (1)(B) or the behavioral change pro-
14	grams described in paragraph (2).
15	"(ii) Qualified incentive ben-
16	EFIT.—For purposes of clause (i), the
17	term 'qualified incentive benefit' means
18	any benefit which is approved by the Sec-
19	retary of Health and Human Services.
20	Such benefit may include an adjustment in
21	health insurance premiums or co-pays.
22	"(C) Employee input.—The opportunity
23	for employees to participate in the management
24	of any qualified wellness program or qualified

1	small business wellness program to which this
2	section applies.
3	"(d) Participation Requirement.—
4	"(1) In general.—No credit shall be allowed
5	under subsection (a) unless the Secretary of Health
6	and Human Services certifies, as a part of any cer-
7	tification described in subsection (b), that each
8	wellness program component of the qualified
9	wellness program or qualified small business
10	wellness program applies to all qualified employees
11	of the employer.
12	"(2) Qualified employee.—For purposes of
13	paragraph (1), the term 'qualified employee' means
14	an employee who works an average of not less than
15	25 hours per week during the taxable year.
16	"(e) Other Definitions and Special Rules.—
17	For purposes of this section—
18	"(1) Employee and employer.—
19	"(A) Partners and partnerships.—
20	The term 'employee' includes a partner and the
21	term 'employer' includes a partnership.
22	"(B) CERTAIN RULES TO APPLY.—Rules
23	similar to the rules of section 52 shall apply.
24	"(2) Small business employer.—

1	"(A) IN GENERAL.—The term 'small busi-
2	ness employer' means, with respect to any tax-
3	able year, an employer who employed an aver-
4	age of 200 or fewer employees on business days
5	during such taxable year.
6	"(B) Controlled Groups.—For pur-
7	poses of subparagraph (A), all persons treated
8	as a single employer under subsection (b), (c),
9	(m), or (o) of section 414 shall be treated as a
10	single employer.
11	"(3) CERTAIN COSTS NOT INCLUDED.—Costs
12	paid or incurred by an employer or small business
13	employer for food or health insurance shall not be
14	taken into account under subsection (a).
15	"(f) Portion of Credit Made Refundable.—
16	"(1) In general.—In the case of an eligible
17	employer of an employee, the aggregate credits al-
18	lowed to a taxpayer under subpart C shall be in-
19	creased by the lesser of—
20	"(A) the credit which would be allowed
21	under this section without regard to this sub-
22	section and the limitation under section 38(c),
23	or
24	"(B) the amount by which the aggregate
25	amount of credits allowed by this subpart (de-

1	termined without regard to this subsection)
2	would increase if the limitation imposed by sec-
3	tion 38(c) for any taxable year were increased
4	by the amount of employer payroll taxes im-
5	posed on the taxpayer during the calendar year
6	in which the taxable year begins.
7	The amount of the credit allowed under this sub-
8	section shall not be treated as a credit allowed under
9	this subpart and shall reduce the amount of the
10	credit otherwise allowable under subsection (a) with-
11	out regard to section 38(c).
12	"(2) Eligible employer.—For purposes of
13	this subsection, the term 'eligible employer' means
14	an employer or small business employer which is—
15	"(A) a State or political subdivision there-
16	of, the District of Columbia, a possession of the
17	United States, or an agency or instrumentality
18	of any of the foregoing, or
19	"(B) any organization described in section
20	501(c) of the Internal Revenue Code of 1986
21	which is exempt from taxation under section
22	501(a) of such Code.
23	"(3) Employer payroll taxes.—For pur-
24	poses of this subsection—

1	"(A) IN GENERAL.—The term 'employer
2	payroll taxes' means the taxes imposed by—
3	"(i) section 3111(b), and
4	"(ii) sections 3211(a) and 3221(a)
5	(determined at a rate equal to the rate
6	under section 3111(b)).
7	"(B) Special rule.—A rule similar to
8	the rule of section 24(d)(2)(C) shall apply for
9	purposes of subparagraph (A).
10	"(g) Termination.—This section shall not apply to
11	any amount paid or incurred after December 31, 2016.".
12	(b) Treatment as General Business Credit.—
13	Subsection (b) of section 38 of the Internal Revenue Code
14	of 1986 (relating to general business credit) is amended
15	by striking "and" at the end of paragraph (29), by strik-
16	ing the period at the end of paragraph (30) and inserting
17	", and", and by adding at the end the following:
18	"(31) the wellness program credit determined
19	under section 45N.".
20	(c) Denial of Double Benefit.—Section 280C of
21	the Internal Revenue Code of 1986 (relating to certain
22	expenses for which credits are allowable) is amended by
23	adding at the end the following new subsection:
24	"(e) Wellness Program Credit.—

1 "(1) IN GENERAL.—No deduction shall be allowed for that portion of the costs paid or incurred for a qualified wellness program (within the meaning of section 45N) or a qualified small business wellness program (within the meaning of such section) allowable as a deduction for the taxable year which is equal to the amount of the credit allowable for the taxable year under section 45N.

- "(2) Similar rule where taxpayer capitalizes rather than deducts expenses.—If—
 - "(A) the amount of the credit determined for the taxable year under section 45N, exceeds
 - "(B) the amount allowable as a deduction for such taxable year for a qualified wellness program or a qualified small business wellness program, the amount chargeable to capital account for the taxable year for such expenses shall be reduced by the amount of such excess.
- "(3) Controlled Groups.—In the case of a corporation which is a member of a controlled group of corporations (within the meaning of section 41(f)(5)) or a trade or business which is treated as being under common control with other trades or business (within the meaning of section 41(f)(1)(B)), this subsection shall be applied under

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- 1 rules prescribed by the Secretary similar to the rules
- 2 applicable under subparagraphs (A) and (B) of sec-
- 3 tion 41(f)(1).".
- 4 (d) CLERICAL AMENDMENT.—The table of sections
- 5 for subpart D of part IV of subchapter A of chapter 1
- 6 of the Internal Revenue Code of 1986 is amended by add-
- 7 ing at the end the following:

"Sec. 45N. Wellness program credit.".

- 8 (e) Effective Date.—The amendments made by
- 9 this section shall apply to taxable years beginning after
- 10 December 31, 2006.
- 11 (f) Outreach.—
- 12 (1) IN GENERAL.—The Secretary of the Treas-
- ury, in conjunction with the Director of the Centers
- for Disease Control and members of the business
- 15 community, shall institute an outreach program to
- inform businesses about the availability of the
- wellness program credit under section 45N of the
- 18 Internal Revenue Code of 1986.
- 19 (2) Authorization of appropriations.—
- There are authorized to be appropriated such sums
- as are necessary to carry out the outreach program
- described in paragraph (1).
- 23 (g) Restoration of Highest Income Tax Rate
- 24 TO PRE-2001 LEVEL.—Section 1(i)(2) of the Internal
- 25 Revenue Code of 1986 (relating to reductions in rates

1	after June 30, 2001) is amended by adding at the end
2	the following new flush sentence:
3	"In the case of taxable years beginning after 2006,
4	the last item in the fourth column in the preceding
5	table shall be applied by substituting '39.6%' for
6	'35.0%'".
7	(h) Effective Date.—The amendments made by
8	this section shall apply to taxable years beginning after
9	December 31, 2006.
10	SEC. 203. INCOME EXCLUSION FOR EMPLOYER-PROVIDED
11	OFF-PREMISES HEALTH CLUB SERVICES.
12	(a) Treatment as Fringe Benefit.—Subpara-
13	graph (A) of section 132(j)(4) of the Internal Revenue
14	Code of 1986 (relating to on-premises gyms and other ath-
15	letic facilities) is amended to read as follows:
16	"(A) In general.—Gross income shall
17	not include—
18	"(i) the value of any on-premises ath-
19	letic facility provided by an employer to its
20	employees, and
21	"(ii) fees or membership expenses
22	paid by an employer to an athletic or fit-
23	
	ness facility described in subparagraph (C)

1	extent that such fees or expenses do not
2	exceed \$900.
3	The preceding sentence shall apply with respect
4	to any highly compensated employee only if ac-
5	cess to the facility is available on substantially
6	the same terms to each member of a group of
7	employees which is defined under a reasonable
8	classification set up by the employer which does
9	not discriminate in favor of highly compensated
10	employees.".
11	(b) Athletic Facilities Described.—Paragraph
12	(4) of section 132(j) of such Code is amended by adding
13	at the end the following new subparagraph:
14	"(C) CERTAIN ATHLETIC OR FITNESS FA-
15	CILITIES DESCRIBED.—For purposes of sub-
16	paragraph (A)(ii), an athletic or fitness facility
17	described in this subparagraph is a facility—
18	"(i) providing instruction in a pro-
19	gram of physical exercise or offering facili-
20	ties for the preservation, maintenance, en-
21	couragement, or development of physical
22	fitness,
23	"(ii) which is not a private club owned
24	and operated by its members,

1	"(iii) which does not offer golf, hunt-
2	ing, sailing, or riding facilities,
3	"(iv) whose health or fitness facility is
4	not incidental to its overall function and
5	purpose, and
6	"(v) which is fully compliant with the
7	State of jurisdiction and Federal anti-dis-
8	criminations laws.".
9	(c) Employer Deduction for Dues to Certain
10	ATHLETIC FACILITIES.—
11	(1) In General.—Paragraph (3) of section
12	274(a) of such Code (relating to denial of deduction
13	for club dues) is amended—
14	(A) by striking "Notwithstanding" and in-
15	serting the following:
16	"(A) In General.—Notwithstanding",
17	and
18	(B) by adding at the end the following new
19	subparagraph:
20	"(B) Exception for athletic facili-
21	TIES.—This paragraph shall not apply to fees
22	or dues paid to athletic or fitness facilities
23	(within the meaning of section $132(j)(4)(C)$) to
24	the extent that such fees or dues do not exceed
25	\$900 for any membership.".

1	(2) Conforming Amendment.—Section
2	274(e)(4) of such Code is amended by striking "sub-
3	section (a)(3)" and by inserting "subsection
4	(a)(3)(A)".
5	(d) Effective Date.—The amendments made by
6	this section shall apply to taxable years beginning after
7	the date of the enactment of this Act.
8	SEC. 204. CDC AND EMPLOYER-BASED WELLNESS PRO-
9	GRAMS.
10	Title III of the Public Health Service Act (42 U.S.C.
11	241 et seq.) is amended by adding at the end the fol-
12	lowing:
	"DADED CDC AND EMDLOVED DACED
13	"PART R—CDC AND EMPLOYER-BASED
13 14	WELLNESS PROGRAMS
14	WELLNESS PROGRAMS
14 15	WELLNESS PROGRAMS "SEC. 399Z-1. EMPLOYER-BASED WELLNESS BEST PRAC-
14 15 16 17	WELLNESS PROGRAMS "SEC. 399Z-1. EMPLOYER-BASED WELLNESS BEST PRAC- TICES.
14 15 16 17	WELLNESS PROGRAMS "SEC. 399Z-1. EMPLOYER-BASED WELLNESS BEST PRACTICES. "(a) IN GENERAL.—The Director of the Centers for
14 15 16 17	WELLNESS PROGRAMS "SEC. 399Z-1. EMPLOYER-BASED WELLNESS BEST PRACTICES. "(a) IN GENERAL.—The Director of the Centers for Disease Control and Prevention shall conduct a study that
14 15 16 17 18	WELLNESS PROGRAMS "SEC. 399Z-1. EMPLOYER-BASED WELLNESS BEST PRACTICES. "(a) IN GENERAL.—The Director of the Centers for Disease Control and Prevention shall conduct a study that analyzes employer-based wellness programs and deter-
14 15 16 17 18 19 20	WELLNESS PROGRAMS "SEC. 399Z-1. EMPLOYER-BASED WELLNESS BEST PRACTICES. "(a) IN GENERAL.—The Director of the Centers for Disease Control and Prevention shall conduct a study that analyzes employer-based wellness programs and determines—
14 15 16 17 18 19 20 21	WELLNESS PROGRAMS "SEC. 399Z-1. EMPLOYER-BASED WELLNESS BEST PRACTICES. "(a) IN GENERAL.—The Director of the Centers for Disease Control and Prevention shall conduct a study that analyzes employer-based wellness programs and determines— "(1) best practices of such programs that im-
14 15 16 17 18 19 20 21	WELLNESS PROGRAMS "SEC. 399Z-1. EMPLOYER-BASED WELLNESS BEST PRACTICES. "(a) In General.—The Director of the Centers for Disease Control and Prevention shall conduct a study that analyzes employer-based wellness programs and determines— "(1) best practices of such programs that impact and sustain behavior change in employees;

1	"(3) the return to employers on the investment
2	made by such employers in such programs.
3	"(b) Report.—After completing the study under
4	subsection (a), the Director of the Centers for Disease
5	Control and Prevention shall submit to Congress not later
6	than 1 year after the date of enactment of this part—
7	"(1) a report that includes recommendations of
8	effective employer-based wellness programs; and
9	"(2) an Employer Wellness Model that is sup-
10	ported by the Centers for Disease Control and Pre-
11	vention.
12	"SEC. 399Z-2. WORKPLACE WELLNESS EDUCATION CAM-
12 13	"SEC. 399Z-2. WORKPLACE WELLNESS EDUCATION CAM- PAIGN FOR EMPLOYERS.
13	PAIGN FOR EMPLOYERS.
13 14 15	PAIGN FOR EMPLOYERS. "The Director of the Centers for Disease Control and
13 14 15	PAIGN FOR EMPLOYERS. "The Director of the Centers for Disease Control and Prevention, in coordination with relevant worksite health
13 14 15 16 17	PAIGN FOR EMPLOYERS. "The Director of the Centers for Disease Control and Prevention, in coordination with relevant worksite health promotion organizations, shall conduct an educational
13 14 15 16 17	PAIGN FOR EMPLOYERS. "The Director of the Centers for Disease Control and Prevention, in coordination with relevant worksite health promotion organizations, shall conduct an educational campaign to make employers, employer groups, and other
13 14 15 16 17	PAIGN FOR EMPLOYERS. "The Director of the Centers for Disease Control and Prevention, in coordination with relevant worksite health promotion organizations, shall conduct an educational campaign to make employers, employer groups, and other interested parties aware of the benefits of employer-based
13 14 15 16 17 18	PAIGN FOR EMPLOYERS. "The Director of the Centers for Disease Control and Prevention, in coordination with relevant worksite health promotion organizations, shall conduct an educational campaign to make employers, employer groups, and other interested parties aware of the benefits of employer-based wellness programs. Such campaign shall include informations.

1	"SEC. 399Z-3. EVALUATION OF EMPLOYER-BASED
2	WELLNESS PROGRAMS.
3	"The Director of the Centers for Disease Control and
4	Prevention shall enter into contracts with entities to—
5	"(1) provide employers with technical assistance
6	in evaluating such employers' employer-based
7	wellness programs; and
8	"(2) train employers on how to evaluate such
9	employers' employer-based wellness programs.
10	"SEC. 399Z-4. REQUIREMENTS BASED ON APPROPRIATED
11	FUNDS.
12	"The Director of the Centers for Disease Control and
13	Prevention shall be required to carry out the activities in
14	sections 399Z-1, 399Z-2, and 399Z-3 only if funds are
15	appropriated to carry out such sections.".
16	Subtitle B—Healthy Communities
17	SEC. 211. HEALTHY COMMUNITY GRANTS.
18	Part P of title III of the Public Health Service Act
19	(42 U.S.C. 280g et seq.) is amended by adding at the end
20	the following:
21	"SEC. 399P. HEALTHY COMMUNITY GRANTS.
22	"(a) Establishment.—The Secretary, acting
23	through the Director of the Centers for Disease Control
24	and Prevention and in coordination with the Directors of
25	other appropriate Federal agencies, shall award competi-
26	tive grants to eligible entities for the purpose of planning

1	and implementing programs that seek to promote indi-
2	vidual and community health and to prevent the incidence
3	of chronic disease.
4	"(b) Eligibility.—
5	"(1) In general.—To be eligible to receive a
6	grant under this section an entity shall—
7	"(A) be—
8	"(i) a city, county, or Indian tribe;
9	"(ii) a local or tribal educational
10	agency;
11	"(iii) an accredited university, college,
12	or community college;
13	"(iv) a federally qualified health cen-
14	ter;
15	"(v) a local health department;
16	"(vi) a health care provider;
17	"(vii) a community-based organiza-
18	tion; or
19	"(viii) any other entity determined ap-
20	propriate by the Secretary, including a
21	consortia or partnership of entities de-
22	scribed in any of clauses (i) through (vii);
23	"(B) prepare and submit an application in
24	accordance with paragraph (2); and

1	"(C) provide assurances that the entity will
2	contribute the non-Federal share as required
3	under paragraph (3) to the cost of the activities
4	carried out under the grant.
5	"(2) Application.—
6	"(A) In general.—An entity desiring a
7	grant under this section shall submit an appli-
8	cation to the Secretary at such time, in such
9	manner, and containing such information as the
10	Secretary may require, including a plan that
11	meets the requirements of subparagraph (B).
12	"(B) Plan.—A plan meets the require-
13	ments of this subparagraph if such plan, at a
14	minimum, includes information regarding—
15	"(i)(I) programs or community-based
16	activities that the applicant proposes to
17	carry out with funds received under this
18	section and which seek to prevent and re-
19	duce the incidence of—
20	"(aa) overweight and obesity, or
21	chronic diseases associated with over-
22	weight and obesity;
23	"(bb) tobacco use; or
24	"(cc) mental illness; or

1	"(II) other such activities, as deter-
2	mined appropriate by the Secretary, that
3	are consistent with the goals of promoting
4	individual and community health and pre-
5	venting chronic disease; and
6	"(ii) the manner in which the appli-
7	cant will evaluate the effectiveness of the
8	program or activities carried out under this
9	section.
10	"(3) Non-federal share.—To be eligible to
11	receive a grant under this section, an entity shall
12	provide a non-Federal contribution, in cash or in
13	kind, to the costs of activities under the grant in an
14	amount that is equal to not less than 25 percent of
15	the costs of such activities.
16	"(c) Use of Funds.—An entity that receives a grant
17	under this section shall use the amount made available
18	under the grant to carry out community-based activities,
19	including—
20	"(1) activities that seek to promote individual
21	health and community wellness and to prevent and
22	reduce the incidence of health problems and chronic
23	diseases associated with—
24	"(A) being overweight or obese;
25	"(B) tobacco use; or

1	"(C) mental illness; or
2	"(2) other activities undertaken with the goals
3	of health promotion and chronic disease prevention,
4	as determined appropriate by the Secretary.
5	"(d) Priority.—In awarding grants under sub-
6	section (a), the Secretary shall give priority to—
7	"(1) entities that demonstrate that they have
8	previously applied successfully for funds to carry out
9	activities that seek to promote individual and com-
10	munity health and to prevent the incidence of chron-
11	ic disease and that can cite published and peer-re-
12	viewed research demonstrating that the activities
13	that the entity proposes to carry out under this sub-
14	section are effective;
15	"(2) entities that will carry out programs or ac-
16	tivities that seek to accomplish a goal or goals set
17	by the State in the Healthy People 2010 plan of the
18	State;
19	"(3) entities that provide non-Federal contribu-
20	tions, either in cash or in kind, to the costs of fund-
21	ing activities under the grant;
22	"(4) entities that develop comprehensive plans
23	that include a strategy for extending program activi-
24	ties developed under this section in the years fol-

1	lowing the fiscal years for which they receive grants
2	under this section;
3	"(5) entities located in communities that are
4	medically underserved, as determined by the Sec-
5	retary;
6	"(6) entities located in areas where the average
7	poverty rate is 150 or higher than the average pov-
8	erty rate in the State involved, as determined by the
9	Secretary; and
10	"(7) entities that submit plans that exhibit
11	multisectoral, cooperative conduct that includes the
12	involvement of a broad range of stakeholders, includ-
13	ing—
14	"(A) community-based organizations;
15	"(B) local governments;
16	"(C) local educational agencies;
17	"(D) the private sector;
18	"(E) State or local departments of health;
19	"(F) accredited colleges, universities, and
20	community colleges;
21	"(G) health care providers;
22	"(H) State and local departments of trans-
23	portation and city planning; and
24	"(I) other entities determined appropriate
25	by the Secretary.

- 1 "(e) Technical Assistance.—From amounts ap-
- 2 propriated to carry out this section, the Secretary may re-
- 3 serve not more than 10 percent for each fiscal year to pro-
- 4 vide entities receiving grants under this section with tech-
- 5 nical assistance in the implementation of the plans re-
- 6 quired under subsection (b)(2)(B).
- 7 "(f) EVALUATION.—From amounts appropriated to
- 8 carry out this section, the Secretary may reserve not to
- 9 exceed 5 percent for each fiscal year for the purpose of
- 10 carrying out evaluations of the activities carried out under
- 11 this section. Not later than 90 days after the completion
- 12 of any such evaluation, the results of such evaluation shall
- 13 be submitted to the relevant authorizing committees of
- 14 Congress and to the Committee on Appropriations of the
- 15 Senate and the Committee on Appropriations of the House
- 16 of Representatives.
- 17 "(g) Limitation on Administrative Costs.—An
- 18 entity may not use more than 10 percent of amounts re-
- 19 ceived under a grant under this section for administrative
- 20 expenses.
- 21 "(h) Supplement Not Supplant.—Amounts pro-
- 22 vided under a grant under this section shall be used to
- 23 supplement, and not supplant, other amounts provided for
- 24 activities of the type to be carried out under this section.

1	"(i) AUTHORIZATION OF APPROPRIATIONS.—There is
2	authorized to be appropriated such sums as may be nec-
3	essary to carry out this section.".
4	SEC. 212. PREVENTIVE MEDICINE AND PUBLIC HEALTH
5	TRAINING GRANT PROGRAM.
6	Part C of title VII of the Public Health Service Act
7	is amended by inserting after section 747 (42 U.S.C.
8	293k) the following:
9	"SEC. 747A. PREVENTIVE MEDICINE AND PUBLIC HEALTH
10	TRAINING GRANT PROGRAM.
11	"(a) Grants.—The Secretary may award grants to,
12	or enter into contracts with, eligible entities to provide
13	training to graduate medical residents in preventive medi-
14	cine and public health.
15	"(b) Eligibility.—To be eligible to receive a grant
16	or contract under subsection (a), an entity shall—
17	"(1) be a school of public health, public health
18	department, school of medicine or osteopathic medi-
19	cine, public or private hospital, or public or private
20	non-profit entity; and
21	"(2) submit to the Secretary an application at
22	such time, in such manner, and containing such in-
23	formation as the Secretary may require.
24	"(e) Preference and Special Consideration —

"(1) Preference.—In awarding grants or contracts under this section, the Secretary shall give preference to one or more eligible entities that have a record of training providers who practice preventive medicine or public health as compared to other eligible entities.

- "(2) Special consideration.—In awarding grants or contracts under this section, the Secretary shall give special consideration to eligible entities that will carry out projects under the grant or contract that train physicians in community-based approaches to combating the incidence rates of obesity, diabetes, heart disease, cancer, and other chronic diseases, and institutions that have a record of training qualified individuals from disadvantaged backgrounds.
- 17 "(d) USE OF FUNDS.—Amounts received under a 18 grant or contract under this section shall be used to—
- "(1) plan, develop, and operate residency programs for preventive medicine or public health;
- "(2) provide financial assistance, including tuition and stipends, to resident physicians (MD or DO) who plan to specialize in preventive medicine or public health;

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1	"(3) defray the costs associated with the plan-
2	ning, development, and operation of preventive medi-
3	cine or public health programs, including the devel-
4	opment of curriculum to be used in such program;
5	and
6	"(4) provide for the improvement of academic
7	administrative units.
8	"(e) Duration of Award.—A grant or contract
9	under this section shall be for a term not to exceed 5
10	years.
11	"(f) Authorization of Appropriations.—There
12	is authorized to be appropriated to carry out this section,
13	\$43,000,000 for fiscal year 2007, and such sums as may
14	be necessary for each succeeding fiscal year.".
15	Subtitle C—Family Smoking
16	Prevention and Control
17	SEC. 221. SHORT TITLE.
18	This subtitle may be cited as the "Family Smoking
19	Prevention and Tobacco Control Act".
20	SEC. 222. FINDINGS.
21	The Congress finds the following:
22	(1) The use of tobacco products by the Nation's
23	children is a pediatric disease of considerable pro-
24	portions that results in new generations of tobacco-
25	dependent children and adults.

- 1 (2) A consensus exists within the scientific and 2 medical communities that tobacco products are in-3 herently dangerous and cause cancer, heart disease, 4 and other serious adverse health effects.
 - (3) Nicotine is an addictive drug.
 - (4) Virtually all new users of tobacco products are under the minimum legal age to purchase such products.
 - (5) Tobacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents.
 - (6) Because past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products are needed.
 - (7) Federal and State governments have lacked the legal and regulatory authority and resources they need to address comprehensively the public health and societal problems caused by the use of tobacco products.
 - (8) Federal and State public health officials, the public health community, and the public at large recognize that the tobacco industry should be subject to ongoing oversight.

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- (9) Under article I, section 8 of the Constitution, the Congress is vested with the responsibility for regulating interstate commerce and commerce with Indian tribes.
 - (10) The sale, distribution, marketing, advertising, and use of tobacco products are activities in and substantially affecting interstate commerce because they are sold, marketed, advertised, and distributed in interstate commerce on a nationwide basis, and have a substantial effect on the Nation's economy.
 - (11) The sale, distribution, marketing, advertising, and use of such products substantially affect interstate commerce through the health care and other costs attributable to the use of tobacco products.
 - (12) It is in the public interest for Congress to enact legislation that provides the Food and Drug Administration with the authority to regulate to-bacco products and the advertising and promotion of such products. The benefits to the American people from enacting such legislation would be significant in human and economic terms.
 - (13) Tobacco use is the foremost preventable cause of premature death in America. It causes over

- 400,000 deaths in the United States each year and approximately 8,600,000 Americans have chronic illnesses related to smoking.
 - (14) Reducing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco induced disease. Such a reduction in youth smoking would also result in approximately \$75,000,000,000 in savings attributable to reduced health care costs.
 - (15) Advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products and these efforts have resulted in increased use of such products by youth. Past efforts to oversee these activities have not been successful in adequately preventing such increased use.
 - (16) In 2002, the tobacco industry spent more than \$12,466,000,000 to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use.

- (17) Tobacco product advertising often misleadingly portrays the use of tobacco as socially acceptable and healthful to minors.
 - (18) Tobacco product advertising is regularly seen by persons under the age of 18, and persons under the age of 18 are regularly exposed to tobacco product promotional efforts.
 - (19) Through advertisements during and sponsorship of sporting events, tobacco has become strongly associated with sports and has become portrayed as an integral part of sports and the healthy lifestyle associated with rigorous sporting activity.
 - (20) Children are exposed to substantial and unavoidable tobacco advertising that leads to favorable beliefs about tobacco use, plays a role in leading young people to overestimate the prevalence of tobacco use, and increases the number of young people who begin to use tobacco.
 - (21) The use of tobacco products in motion pictures and other mass media glamorizes its use for young people and encourages them to use tobacco products.
- (22) Tobacco advertising expands the size of the tobacco market by increasing consumption of to-

- bacco products including tobacco use by young people.
- 3 (23) Children are more influenced by tobacco 4 advertising than adults, they smoke the most adver-5 tised brands.
 - (24) Tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market. Children, who tend to be more price-sensitive than adults, are influenced by advertising and promotion practices that result in drastically reduced cigarette prices.
 - (25) Comprehensive advertising restrictions will have a positive effect on the smoking rates of young people.
 - (26) Restrictions on advertising are necessary to prevent unrestricted tobacco advertising from undermining legislation prohibiting access to young people and providing for education about tobacco use.
 - (27) International experience shows that advertising regulations that are stringent and comprehensive have a greater impact on overall tobacco use and young people's use than weaker or less comprehensive ones.

- (28) Text only requirements, although not as stringent as a ban, will help reduce underage use of tobacco products while preserving the informational function of advertising.
 - (29) It is in the public interest for Congress to adopt legislation to address the public health crisis created by actions of the tobacco industry.
 - (30) The final regulations promulgated by the Secretary of Health and Human Services in the August 28, 1996, issue of the Federal Register (61 Fed. Reg. 44615–44618) for inclusion as part 897 of title 21, Code of Federal Regulations, are consistent with the First Amendment to the United States Constitution and with the standards set forth in the amendments made by this subtitle for the regulation of tobacco products by the Food and Drug Administration and the restriction on the sale and distribution, including access to and the advertising and promotion of, tobacco products contained in such regulations are substantially related to accomplishing the public health goals of this Act.
 - (31) The regulations described in paragraph (30) will directly and materially advance the Federal Government's substantial interest in reducing the number of children and adolescents who use ciga-

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rettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use. An overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18. Tobacco advertising and promotion plays a crucial role in the decision of these minors to begin using tobacco products. Less restrictive and less comprehensive approaches have not and will not be effective in reducing the problems addressed by such regulations. The reasonable restrictions on the advertising and promotion of tobacco products contained in such regulations will lead to a significant decrease in the number of minors using and becoming addicted to those products.

(32) The regulations described in paragraph (30) impose no more extensive restrictions on communication by tobacco manufacturers and sellers than are necessary to reduce the number of children and adolescents who use cigarettes and smokeless tobacco and to prevent the life-threatening health consequences associated with tobacco use. Such regulations are narrowly tailored to restrict those advertising and promotional practices which are most like-

- ly to be seen or heard by youth and most likely to entice them into tobacco use, while affording tobacco manufacturers and sellers ample opportunity to convey information about their products to adult consumers.
 - (33) Tobacco dependence is a chronic disease, one that typically requires repeated interventions to achieve long-term or permanent abstinence.
 - (34) Because the only known safe alternative to smoking is cessation, interventions should target all smokers to help them quit completely.
 - (35) Tobacco products have been used to facilitate and finance criminal activities both domestically and internationally. Illicit trade of tobacco products has been linked to organized crime and terrorist groups.
 - (36) It is essential that the Food and Drug Administration review products sold or distributed for use to reduce risks or exposures associated with to-bacco products and that it be empowered to review any advertising and labeling for such products. It is also essential that manufacturers, prior to marketing such products, be required to demonstrate that such products will meet a series of rigorous criteria, and will benefit the health of the population as a whole,

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taking into account both users of tobacco products and persons who do not currently use tobacco products.

(37) Unless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health to the extent that the individuals, who would otherwise not consume tobacco products or would consume such products less, use tobacco products purporting to reduce risk. Those who use products sold or distributed as modified risk products that do not in fact reduce risk, rather than quitting or reducing their use of tobacco products, have a substantially increased likelihood of suffering disability and premature death. The costs to society of the widespread use of products sold or distributed as modified risk products that do not in fact reduce risk or that increase risk include thousands of unnecessary deaths and injuries and huge costs to our health care system.

(38) As the National Cancer Institute has found, many smokers mistakenly believe that "low tar" and "light" cigarettes cause fewer health problems than other cigarettes. As the National Cancer Institute has also found, mistaken beliefs about the

- health consequences of smoking "low tar" and "light" cigarettes can reduce the motivation to quit smoking entirely and thereby lead to disease and death.
 - (39) Recent studies have demonstrated that there has been no reduction in risk on a population-wide basis from "low tar" and "light" cigarettes and such products may actually increase the risk of to-bacco use.
 - (40) The dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that there is a compelling governmental interest in insuring that statements about modified risk tobacco products are complete, accurate, and relate to the overall disease risk of the product.
 - (41) As the Federal Trade Commission has found, consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended to provide clarification.
 - (42) Permitting manufacturers to make unsubstantiated statements concerning modified risk tobacco products, whether express or implied, even if

- accompanied by disclaimers would be detrimental to
 the public health.
- (43) The only way to effectively protect the 3 4 public health from the dangers of unsubstantiated 5 modified risk tobacco products is to empower the 6 Food and Drug Administration to require that prod-7 ucts that tobacco manufacturers sold or distributed 8 for risk reduction be approved in advance of mar-9 keting, and to require that the evidence relied on to 10 support approval of these products is rigorous.

11 SEC. 223. PURPOSE.

- The purposes of this Act are—
- 13 (1) to provide authority to the Food and Drug
 14 Administration to regulate tobacco products under
 15 the Federal Food, Drug, and Cosmetic Act (21
 16 U.S.C. 301 et seq.), by recognizing it as the primary
 17 Federal regulatory authority with respect to the
 18 manufacture, marketing, and distribution of tobacco
 19 products;
 - (2) to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco;

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- 1 (3) to authorize the Food and Drug Adminis-2 tration to set national standards controlling the 3 manufacture of tobacco products and the identity, 4 public disclosure, and amount of ingredients used in 5 such products;
 - (4) to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products;
 - (5) to vest the Food and Drug Administration with the authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products;
 - (6) in order to ensure that consumers are better informed, to require tobacco product manufacturers to disclose research which has not previously been made available, as well as research generated in the future, relating to the health and dependency effects or safety of tobacco products;
 - (7) to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers;
 - (8) to impose appropriate regulatory controls on the tobacco industry;

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- 1 (9) to promote cessation to reduce disease risk 2 and the social costs associated with tobacco related 3 diseases; and
- 4 (10) to strengthen legislation against illicit 5 trade in tobacco products.

6 SEC. 224. SCOPE AND EFFECT.

- 7 (a) INTENDED EFFECT.—Nothing in this Act (or an 8 amendment made by this Act) shall be construed to—
- 9 (1) establish a precedent with regard to any 10 other industry, situation, circumstance, or legal ac-11 tion; or
- (2) affect any action pending in Federal, State,
 or Tribal court, or any agreement, consent decree, or
 contract of any kind.
- 15 (b) AGRICULTURAL ACTIVITIES.—The provisions of 16 this Act (or an amendment made by this Act) which au-17 thorize the Secretary to take certain actions with regard 18 to tobacco and tobacco products shall not be construed to 19 affect any authority of the Secretary of Agriculture under 20 existing law regarding the growing, cultivation, or curing

22 SEC. 225. SEVERABILITY.

of raw tobacco.

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If any provision of this Act, the amendments made by this Act, or the application of any provision of this Act to any person or circumstance is held to be invalid, the

1	remainder of this Act, the amendments made by this Act
2	and the application of the provisions of this Act to any
3	other person or circumstance shall not be affected and
4	shall continue to be enforced to the fullest extent possible
5	PART I—AUTHORITY OF THE FOOD AND DRUG
6	ADMINISTRATION
7	SEC. 231. AMENDMENT OF FEDERAL FOOD, DRUG, AND
8	COSMETIC ACT.
9	(a) Definition of Tobacco Products.—Section
10	201 of the Federal Food, Drug, and Cosmetic Act (21
11	U.S.C. 321) is amended by adding at the end the fol-
12	lowing:
13	" $(nn)(1)$ The term 'tobacco product' means any prod-
14	uct made or derived from tobacco that is intended for
15	human consumption, including any component, part, or
16	accessory of a tobacco product (except for raw materials
17	other than tobacco used in manufacturing a component
18	part, or accessory of a tobacco product).
19	"(2) The term 'tobacco product' does not mean—
20	"(A) a product in the form of conventional food
21	(including water and chewing gum), a product rep-
22	resented for use as or for use in a conventional food
23	or a product that is intended for ingestion in cap-
24	sule, tablet, softgel, or liquid form; or

1	"(B) an article that is approved or is regulated
2	as a drug by the Food and Drug Administration.
3	"(3) The products described in paragraph (2)(A)
4	shall be subject to chapter IV or chapter V of this Act
5	and the articles described in paragraph (2)(B) shall be
6	subject to chapter V of this Act.
7	"(4) A tobacco product may not be marketed in com-
8	bination with any other article or product regulated under
9	this Act (including a drug, biologic, food, cosmetics, med-
10	ical device, or a dietary supplement).".
11	(b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—
12	The Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13	301 et seq.) is amended—
14	(1) by redesignating chapter IX as chapter X;
15	(2) by redesignating sections 901 through 907
16	as sections 1001 through 1007; and
17	(3) by inserting after section 803 the following:
18	"CHAPTER IX—TOBACCO PRODUCTS
19	"SEC. 900. DEFINITIONS.
20	"In this chapter:
21	"(1) Additive.—The term 'additive' means
22	any substance the intended use of which results or
23	may reasonably be expected to result, directly or in-
24	directly, in its becoming a component or otherwise
25	affecting the characteristic of any tobacco product

- 1 (including any substances intended for use as a fla2 voring, coloring or in producing, manufacturing,
 3 packing, processing, preparing, treating, packaging,
 4 transporting, or holding), except that such term does
 5 not include tobacco or a pesticide chemical residue
 6 in or on raw tobacco or a pesticide chemical.
 - "(2) Brand.—The term 'brand' means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, or packaging, logo, registered trademark or brand name, identifiable pattern of colors, or any combination of such attributes.
 - "(3) CIGARETTE.—The term 'cigarette' has the meaning given that term by section 3(1) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(1)), but also includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.
 - "(4) CIGARETTE TOBACCO.—The term 'cigarette tobacco' means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the require-

- 1 ments for cigarettes shall also apply to cigarette to-2 bacco.
- 3 "(5) COMMERCE.—The term 'commerce' has 4 the meaning given that term by section 3(2) of the 5 Federal Cigarette Labeling and Advertising Act (15 6 U.S.C. 1332(2)).
 - "(6) Counterfeit tobacco product' means a tobacco product (or the container or labeling of such a product) that, without authorization, bears the trademark, trade name, or other identifying mark, imprint or device, or any likeness thereof, of a tobacco product listed in a registration under section 905(i)(1).
 - "(7) DISTRIBUTOR.—The term 'distributor' as regards a tobacco product means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for purposes of this chapter.
 - "(8) ILLICIT TRADE.—The term 'illicit trade' means any practice or conduct prohibited by law which relates to production, shipment, receipt, pos-

- session, distribution, sale, or purchase of tobacco products including any practice or conduct intended to facilitate such activity.
- "(9) Indian tribe.—The term 'Indian tribe'
 has the meaning given such term in section 4(e) of
 the Indian Self Determination and Education Assistance Act (25 U.S.C. 450b(e)).
- 8 "(10) LITTLE CIGAR.—The term 'little cigar' 9 has the meaning given that term by section 3(7) of 10 the Federal Cigarette Labeling and Advertising Act 11 (15 U.S.C. 1332(7)).
 - "(11) NICOTINE.—The term 'nicotine' means the chemical substance named 3-(1–Methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or complex of nicotine.
 - "(12) Package.—The term 'package' means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.
 - "(13) Retailer.—The term 'retailer' means any person who sells tobacco products to individuals for personal consumption, or who operates a facility where self-service displays of tobacco products are permitted.

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- "(14) ROLL-YOUR-OWN TOBACCO.—The term
 'roll-your-own tobacco' means any tobacco which, because of its appearance, type, packaging, or labeling,
 is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.
 - "(15) SMOKE CONSTITUENT.—The term 'smoke constituent' means any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the cigarette to the smoke or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product.
 - "(16) SMOKELESS TOBACCO.—The term 'smokeless tobacco' means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.
 - "(17) STATE.—The term 'State' means any State of the United States and, for purposes of this chapter, includes the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern

1	Mariana Islands, and any other trust territory or
2	possession of the United States.
3	"(18) Tobacco product manufacturer.—
4	Term 'tobacco product manufacturer' means any
5	person, including any repacker or relabeler, who—
6	"(A) manufactures, fabricates, assembles,
7	processes, or labels a tobacco product; or
8	"(B) imports a finished cigarette or
9	smokeless tobacco product for sale or distribu-
10	tion in the United States.
11	"(19) United States.—The term 'United
12	States' means the 50 States of the United States of
13	America and the District of Columbia, the Common-
14	wealth of Puerto Rico, Guam, the Virgin Islands,
15	American Samoa, Wake Island, Midway Islands,
16	Kingman Reef, Johnston Atoll, the Northern Mar-
17	iana Islands, and any other trust territory or posses-
18	sion of the United States.
19	"SEC. 901. FDA AUTHORITY OVER TOBACCO PRODUCTS.
20	"(a) In General.—Tobacco products shall be regu-
21	lated by the Secretary under this chapter and shall not
22	be subject to the provisions of chapter V, unless—
23	"(1) such products are intended for use in the
24	diagnosis, cure, mitigation, treatment, or prevention

1	of disease (within the meaning of section
2	201(g)(1)(B) or section $201(h)(2)$; or
3	"(2) a claim is made for such products under
4	section $201(g)(1)(C)$ or $201(h)(3)$;
5	other than modified risk tobacco products approved
6	in accordance with section 911.
7	"(b) APPLICABILITY.—This chapter shall apply to all
8	tobacco products subject to the regulations referred to in
9	section 232 of the Family Smoking Prevention and To-
10	bacco Control Act, and to any other tobacco products that
11	the Secretary by regulation deems to be subject to this
12	chapter.
13	"(c) Scope.—
14	"(1) In general.—Nothing in this chapter, or
15	any policy issued or regulation promulgated there-
16	under, or the Family Smoking Prevention and To-
17	bacco Control Act, shall be construed to affect the
18	Secretary's authority over, or the regulation of,
19	products under this Act that are not tobacco prod-
20	ucts under chapter V or any other chapter.
21	"(2) Limitation of Authority.—
22	"(A) In general.—The provisions of this
23	chapter shall not apply to tobacco leaf that is
24	not in the possession of a manufacturer of to-
25	bacco products, or to the producers of tobacco

leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor
shall any employee of the Food and Drug Administration have any authority to enter onto a
farm owned by a producer of tobacco leaf without the written consent of such producer.

- "(B) EXCEPTION.—Notwithstanding any other provision of this subparagraph, if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this chapter in the producer's capacity as a manufacturer.
- "(C) RULE OF CONSTRUCTION.—Nothing in this chapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof, other than activities by a manufacturer affecting production.

21 "SEC. 902. ADULTERATED TOBACCO PRODUCTS.

- 22 "A tobacco product shall be deemed to be adulterated 23 if—
- 24 "(1) it consists in whole or in part of any filthy, 25 putrid, or decomposed substance, or is otherwise

- 1 contaminated by any added poisonous or added dele-2 terious substance that may render the product inju-3 rious to health; "(2) it has been prepared, packed, or held 4 5 under insanitary conditions whereby it may have 6 been contaminated with filth, or whereby it may 7 have been rendered injurious to health; "(3) its package is composed, in whole or in 8 9 part, of any poisonous or deleterious substance 10 which may render the contents injurious to health; 11 "(4) it is, or purports to be or is represented 12 as, a tobacco product which is subject to a tobacco 13 product standard established under section 907 un-14 less such tobacco product is in all respects in con-15 formity with such standard; "(5)(A) it is required by section 910(a) to have 16 17 premarket approval and does not have an approved 18 application in effect; or 19 "(B) it is in violation of the order approving 20 such an application; "(6) the methods used in, or the facilities or 21 22
 - "(6) the methods used in, or the facilities or controls used for, its manufacture, packing or storage are not in conformity with applicable requirements under section 906(e)(1) or an applicable con-

1	dition prescribed by an order under section
2	906(e)(2); or
3	"(7) it is in violation of section 911.
4	"SEC. 903. MISBRANDED TOBACCO PRODUCTS.
5	"(a) In General.—A tobacco product shall be
6	deemed to be misbranded—
7	"(1) if its labeling is false or misleading in any
8	particular;
9	"(2) if in package form unless it bears a label
10	containing—
11	"(A) the name and place of business of the
12	tobacco product manufacturer, packer, or dis-
13	tributor;
14	"(B) an accurate statement of the quantity
15	of the contents in terms of weight, measure, or
16	numerical count;
17	"(C) an accurate statement of the percent-
18	age of the tobacco used in the product that is
19	domestically grown tobacco and the percentage
20	that is foreign grown tobacco; and
21	"(D) the statement required under section
22	921(a), except that under subparagraph (B)
23	reasonable variations shall be permitted, and
24	exemptions as to small packages shall be estab-

lished, by regulations prescribed by the Secretary;

"(3) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements or designs in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

"(4) if it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name prominently printed in type as required by the Secretary by regulation;

"(5) if the Secretary has issued regulations requiring that its labeling bear adequate directions for use, or adequate warnings against use by children, that are necessary for the protection of users unless its labeling conforms in all respects to such regulations;

"(6) if it was manufactured, prepared, propagated, compounded, or processed in any State in an establishment not duly registered under section 905(b), 905(c), 905(d), or 905(h), if it was not in-

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1	cluded in a list required by section 905(i), if a notice
2	or other information respecting it was not provided
3	as required by such section or section 905(j), or if
4	it does not bear such symbols from the uniform sys-
5	tem for identification of tobacco products prescribed
6	under section 905(e) as the Secretary by regulation
7	requires;
8	"(7) if, in the case of any tobacco product dis-
9	tributed or offered for sale in any State—
10	"(A) its advertising is false or misleading
11	in any particular; or
12	"(B) it is sold or distributed in violation of
13	regulations prescribed under section 906(d);
14	"(8) unless, in the case of any tobacco product
15	distributed or offered for sale in any State, the man-
16	ufacturer, packer, or distributor thereof includes in
17	all advertisements and other descriptive printed mat-
18	ter issued or caused to be issued by the manufac-
19	turer, packer, or distributor with respect to that to-
20	bacco product—
21	"(A) a true statement of the tobacco prod-
22	uct's established name as described in para-
23	graph (4), printed prominently; and
24	"(B) a brief statement of—

1	"(i) the uses of the tobacco product
2	and relevant warnings, precautions, side
3	effects, and contraindications; and
4	"(ii) in the case of specific tobacco
5	products made subject to a finding by the
6	Secretary after notice and opportunity for
7	comment that such action is appropriate to
8	protect the public health, a full description
9	of the components of such tobacco product
10	or the formula showing quantitatively each
11	ingredient of such tobacco product to the
12	extent required in regulations which shall
13	be issued by the Secretary after an oppor-
14	tunity for a hearing;
15	"(9) if it is a tobacco product subject to a to-
16	bacco product standard established under section
17	907, unless it bears such labeling as may be pre-
18	scribed in such tobacco product standard; or
19	"(10) if there was a failure or refusal—
20	"(A) to comply with any requirement pre-
21	scribed under section 904 or 908; or
22	"(B) to furnish any material or informa-
23	tion required under section 909.
24	"(b) Prior Approval of Label Statements.—
25	The Secretary may, by regulation, require prior approval

- 1 of statements made on the label of a tobacco product. No
- 2 regulation issued under this subsection may require prior
- 3 approval by the Secretary of the content of any advertise-
- 4 ment, except for modified risk tobacco products as pro-
- 5 vided in section 911. No advertisement of a tobacco prod-
- 6 uct published after the date of enactment of the Family
- 7 Smoking Prevention and Tobacco Control Act shall, with
- 8 respect to the language of label statements as prescribed
- 9 under section 4 of the Cigarette Labeling and Advertising
- 10 Act and section 3 of the Comprehensive Smokeless To-
- 11 bacco Health Education Act of 1986 or the regulations
- 12 issued under such sections, be subject to the provisions
- 13 of sections 12 through 15 of the Federal Trade Commis-
- 14 sion Act (15 U.S.C. 52 through 55).
- 15 "SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE
- 16 SECRETARY.
- 17 "(a) Requirement.—Not later than 6 months after
- 18 the date of enactment of the Family Smoking Prevention
- 19 and Tobacco Control Act, each tobacco product manufac-
- 20 turer or importer, or agents thereof, shall submit to the
- 21 Secretary the following information:
- 22 "(1) A listing of all ingredients, including to-
- bacco, substances, compounds, and additives that
- are, as of such date, added by the manufacturer to
- 25 the tobacco, paper, filter, or other part of each to-

- bacco product by brand and by quantity in eachbrand and subbrand.
- "(2) A description of the content, delivery, and form of nicotine in each tobacco product measured in milligrams of nicotine in accordance with regulations promulgated by the Secretary in accordance with section 4(a)(4) of the Federal Cigarette Labeling and Advertising Act.
 - "(3) A listing of all constituents, including smoke constituents as applicable, identified by the Secretary as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and by quantity in each brand and subbrand. Effective beginning 2 years after the date of enactment of this chapter, the manufacturer, importer, or agent shall comply with regulations promulgated under section 916 in reporting information under this paragraph, where applicable.
 - "(4) All documents developed after the date of enactment of the Family Smoking Prevention and Tobacco Control Act that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (in-

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- 1 cluding smoke constituents), ingredients, compo-
- 2 nents, and additives.
- 3 "(b) Data Submission.—At the request of the Sec-
- 4 retary, each tobacco product manufacturer or importer of
- 5 tobacco products, or agents thereof, shall submit the fol-
- 6 lowing:
- 7 "(1) Any or all documents (including under-
- 8 lying scientific information) relating to research ac-
- 9 tivities, and research findings, conducted, supported,
- or possessed by the manufacturer (or agents thereof)
- on the health, toxicological, behavioral, or physio-
- logic effects of tobacco products and their constitu-
- ents (including smoke constituents), ingredients,
- components, and additives.
- 15 "(2) Any or all documents (including under-
- lying scientific information) relating to research ac-
- tivities, and research findings, conducted, supported,
- or possessed by the manufacturer (or agents thereof)
- that relate to the issue of whether a reduction in
- risk to health from tobacco products can occur upon
- 21 the employment of technology available or known to
- the manufacturer.
- "(3) Any or all documents (including under-
- 24 lying scientific or financial information) relating to
- 25 marketing research involving the use of tobacco

- 1 products or marketing practices and the effective-
- 2 ness of such practices used by tobacco manufactur-
- 3 ers and distributors.
- 4 An importer of a tobacco product not manufactured in the
- 5 United States shall supply the information required of a
- 6 tobacco product manufacturer under this subsection.
- 7 "(c) Time for Submission.—

under subsection (a).

- 8 "(1) IN GENERAL.—At least 90 days prior to
 9 the delivery for introduction into interstate com10 merce of a tobacco product not on the market on the
 11 date of enactment of the Family Smoking Preven12 tion and Tobacco Control Act, the manufacturer of
 13 such product shall provide the information required
 - "(2) DISCLOSURE OF ADDITIVE.—If at any time a tobacco product manufacturer adds to its tobacco products a new tobacco additive or increases the quantity of an existing tobacco additive, the manufacturer shall, except as provided in paragraph (3), at least 90 days prior to such action so advise the Secretary in writing.
 - "(3) DISCLOSURE OF OTHER ACTIONS.—If at any time a tobacco product manufacturer eliminates or decreases an existing additive, or adds or increases an additive that has by regulation been des-

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ignated by the Secretary as an additive that is not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use, the manufacturer shall within 60 days of such action so advise the Secretary in writing.

"(d) Data List.—

"(1) IN GENERAL.—Not later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Secretary) the list established under subsection (e).

"(2) Consumer research.—The Secretary shall conduct periodic consumer research to ensure that the list published under paragraph (1) is not misleading to lay persons. Not later than 5 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall submit to the appropriate committees of Congress a report on the results of such research, together with recommendations on whether such publication should be continued or modified.

- "(e) Data Collection.—Not later than 12 months 1 2 after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall es-3 4 tablish a list of harmful and potentially harmful constitu-5 ents, including smoke constituents, to health in each to-6 bacco product by brand and by quantity in each brand 7 and subbrand. The Secretary shall publish a public notice 8 requesting the submission by interested persons of sci-9 entific and other information concerning the harmful and potentially harmful constituents in tobacco products and 10
- 12 "SEC. 905. ANNUAL REGISTRATION.

tobacco smoke.

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- "(a) Definitions.—In this section:
- 14 "(1) MANUFACTURE, PREPARATION, 15 COMPOUNDING, OR PROCESSING.—The term 'manufacture, preparation, compounding, or processing' 16 17 shall include repackaging or otherwise changing the 18 container, wrapper, or labeling of any tobacco prod-19 uct package in furtherance of the distribution of the 20 tobacco product from the original place of manufac-21 ture to the person who makes final delivery or sale 22 to the ultimate consumer or user.
 - "(2) NAME.—The term 'name' shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each

- 1 corporate officer and director, and the State of in-
- 2 corporation.
- 3 "(b) REGISTRATION BY OWNERS AND OPERATORS.—
- 4 On or before December 31 of each year every person who
- 5 owns or operates any establishment in any State engaged
- 6 in the manufacture, preparation, compounding, or proc-
- 7 essing of a tobacco product or tobacco products shall reg-
- 8 ister with the Secretary the name, places of business, and
- 9 all such establishments of that person.
- 10 "(c) Registration of New Owners and Opera-
- 11 Tors.—Every person upon first engaging in the manufac-
- 12 ture, preparation, compounding, or processing of a tobacco
- 13 product or tobacco products in any establishment owned
- 14 or operated in any State by that person shall immediately
- 15 register with the Secretary that person's name, place of
- 16 business, and such establishment.
- 17 "(d) Registration of Added Establishments.—
- 18 Every person required to register under subsection (b) or
- 19 (c) shall immediately register with the Secretary any addi-
- 20 tional establishment which that person owns or operates
- 21 in any State and in which that person begins the manufac-
- 22 ture, preparation, compounding, or processing of a tobacco
- 23 product or tobacco products.
- 24 "(e) Uniform Product Identification Sys-
- 25 TEM.—The Secretary may by regulation prescribe a uni-

- 1 form system for the identification of tobacco products and
- 2 may require that persons who are required to list such
- 3 tobacco products under subsection (i) shall list such to-
- 4 bacco products in accordance with such system.
- 5 "(f) Public Access to Registration Informa-
- 6 TION.—The Secretary shall make available for inspection,
- 7 to any person so requesting, any registration filed under
- 8 this section.
- 9 "(g) Biennial Inspection of Registered Estab-
- 10 LISHMENTS.—Every establishment in any State registered
- 11 with the Secretary under this section shall be subject to
- 12 inspection under section 704, and every such establish-
- 13 ment engaged in the manufacture, compounding, or proc-
- 14 essing of a tobacco product or tobacco products shall be
- 15 so inspected by 1 or more officers or employees duly des-
- 16 ignated by the Secretary at least once in the 2-year period
- 17 beginning with the date of registration of such establish-
- 18 ment under this section and at least once in every succes-
- 19 sive 2-year period thereafter.
- 20 "(h) Foreign Establishments Shall Reg-
- 21 ISTER.—Any establishment within any foreign country en-
- 22 gaged in the manufacture, preparation, compounding, or
- 23 processing of a tobacco product or tobacco products, shall
- 24 register under this section under regulations promulgated
- 25 by the Secretary. Such regulations shall require such es-

- 1 tablishment to provide the information required by sub-
- 2 section (i) of this section and shall include provisions for
- 3 registration of any such establishment upon condition that
- 4 adequate and effective means are available, by arrange-
- 5 ment with the government of such foreign country or oth-
- 6 erwise, to enable the Secretary to determine from time to
- 7 time whether tobacco products manufactured, prepared,
- 8 compounded, or processed in such establishment, if im-
- 9 ported or offered for import into the United States, shall
- 10 be refused admission on any of the grounds set forth in
- 11 section 801(a).

12 "(i) Registration Information.—

- 13 "(1) Product list.—Every person who reg-
- isters with the Secretary under subsection (b), (c),
- (d), or (h) shall, at the time of registration under
- any such subsection, file with the Secretary a list of
- all tobacco products which are being manufactured,
- prepared, compounded, or processed by that person
- for commercial distribution and which has not been
- included in any list of tobacco products filed by that
- 21 person with the Secretary under this paragraph or
- paragraph (2) before such time of registration. Such
- list shall be prepared in such form and manner as
- 24 the Secretary may prescribe and shall be accom-
- panied by—

1 "(A) in the case of a tobacco product con2 tained in the applicable list with respect to
3 which a tobacco product standard has been es4 tablished under section 907 or which is subject
5 to section 910, a reference to the authority for
6 the marketing of such tobacco product and a
7 copy of all labeling for such tobacco product;

"(B) in the case of any other tobacco product contained in an applicable list, a copy of all consumer information and other labeling for such tobacco product, a representative sampling of advertisements for such tobacco product, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and

"(C) if the registrant filing a list has determined that a tobacco product contained in such list is not subject to a tobacco product standard established under section 907, a brief statement of the basis upon which the registrant made such determination if the Secretary requests such a statement with respect to that particular tobacco product.

"(2) BIANNUAL REPORT OF ANY CHANGE IN PRODUCT LIST.—Each person who registers with the

Secretary under this section shall report to the Secretary once during the month of June of each year and once during the month of December of each year the following:

"(A) A list of each tobacco product introduced by the registrant for commercial distribution which has not been included in any list previously filed by that person with the Secretary under this subparagraph or paragraph (1). A list under this subparagraph shall list a tobacco product by its established name and shall be accompanied by the other information required by paragraph (1).

"(B) If since the date the registrant last made a report under this paragraph that person has discontinued the manufacture, preparation, compounding, or processing for commercial distribution of a tobacco product included in a list filed under subparagraph (A) or paragraph (1), notice of such discontinuance, the date of such discontinuance, and the identity of its established name.

"(C) If since the date the registrant reported under subparagraph (B) a notice of discontinuance that person has resumed the manu-

1 facture, preparation, compounding, or proc-2 essing for commercial distribution of the tobacco product with respect to which such notice 3 4 of discontinuance was reported, notice of such resumption, the date of such resumption, the 6 identity of such tobacco product by established name, and other information required by para-7 8 graph (1), unless the registrant has previously 9 reported such resumption to the Secretary 10 under this subparagraph.

- "(D) Any material change in any information previously submitted under this paragraph or paragraph (1).
- 14 "(j) Report Preceding Introduction of Cer-15 tain Substantially-Equivalent Products Into 16 Interstate Commerce.—

"(1) IN GENERAL.—Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product intended for human use that was not commercially marketed (other than for test marketing) in the United States as of June 1, 2003, shall, at least 90 days prior to making such introduction or delivery, report to the Secretary (in

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1	such form and manner as the Secretary shall pre-
2	scribe)—
3	"(A) the basis for such person's determina-
4	tion that the tobacco product is substantially
5	equivalent, within the meaning of section 910
6	to a tobacco product commercially marketed
7	(other than for test marketing) in the United
8	States as of June 1, 2003, that is in compliance
9	with the requirements of this Act; and
10	"(B) action taken by such person to com-
11	ply with the requirements under section 907
12	that are applicable to the tobacco product.
13	"(2) Application to certain post june 1,
14	2003 PRODUCTS.—A report under this subsection for
15	a tobacco product that was first introduced or deliv-
16	ered for introduction into interstate commerce for
17	commercial distribution in the United States after
18	June 1, 2003, and prior to the date that is 15
19	months after the date of enactment of the Family
20	Smoking Prevention and Tobacco Control Act shall
21	be submitted to the Secretary not later than 15
22	months after such date of enactment.
23	"(3) Exemptions.—
24	"(A) IN GENERAL.—The Secretary may by
25	regulation, exempt from the requirements of

1	this subsection tobacco products that are modi-
2	fied by adding or deleting a tobacco additive, or
3	increasing or decreasing the quantity of an ex-
4	isting tobacco additive, if the Secretary deter-
5	mines that—
6	"(i) such modification would be a
7	minor modification of a tobacco product
8	authorized for sale under this Act;
9	"(ii) a report under this subsection is
10	not necessary to ensure that permitting the
11	tobacco product to be marketed would be
12	appropriate for protection of the public
13	health; and
14	"(iii) an exemption is otherwise appro-
15	priate.
16	"(B) REGULATIONS.—Not later than 9
17	months after the date of enactment of the Fam-
18	ily Smoking Prevention and Tobacco Control
19	Act, the Secretary shall issue regulations to im-
20	plement this paragraph.
21	"SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL
22	OF TOBACCO PRODUCTS.
23	"(a) In General.—Any requirement established by
24	or under section 902, 903, 905, or 909 applicable to a
25	tobacco product shall apply to such tobacco product until

- 1 the applicability of the requirement to the tobacco product
- 2 has been changed by action taken under section 907, sec-
- 3 tion 910, section 911, or subsection (d) of this section,
- 4 and any requirement established by or under section 902,
- 5 903, 905, or 909 which is inconsistent with a requirement
- 6 imposed on such tobacco product under section 907, sec-
- 7 tion 910, section 911, or subsection (d) of this section
- 8 shall not apply to such tobacco product.
- 9 "(b) Information on Public Access and Com-
- 10 MENT.—Each notice of proposed rulemaking under section
- 11 907, 908, 909, 910, or 911 or under this section, any
- 12 other notice which is published in the Federal Register
- 13 with respect to any other action taken under any such sec-
- 14 tion and which states the reasons for such action, and
- 15 each publication of findings required to be made in con-
- 16 nection with rulemaking under any such section shall set
- 17 forth—
- 18 "(1) the manner in which interested persons
- may examine data and other information on which
- the notice or findings is based; and
- 21 "(2) the period within which interested persons
- 22 may present their comments on the notice or find-
- ings (including the need therefore) orally or in writ-
- ing, which period shall be at least 60 days but may
- 25 not exceed 90 days unless the time is extended by

- 1 the Secretary by a notice published in the Federal
- 2 Register stating good cause therefore.
- 3 "(c) Limited Confidentiality of Informa-
- 4 TION.—Any information reported to or otherwise obtained
- 5 by the Secretary or the Secretary's representative under
- 6 section 903, 904, 907, 908, 909, 910, 911, or 704, or
- 7 under subsection (e) or (f) of this section, which is exempt
- 8 from disclosure under subsection (a) of section 552 of title
- 9 5, United States Code, by reason of subsection (b)(4) of
- 10 that section shall be considered confidential and shall not
- 11 be disclosed, except that the information may be disclosed
- 12 to other officers or employees concerned with carrying out
- 13 this chapter, or when relevant in any proceeding under
- 14 this chapter.
- 15 "(d) Restrictions.—
- 16 "(1) IN GENERAL.—The Secretary may by reg-
- 17 ulation require restrictions on the sale and distribu-
- tion of a tobacco product, including restrictions on
- the access to, and the advertising and promotion of,
- the tobacco product, if the Secretary determines that
- such regulation would be appropriate for the protec-
- tion of the public health. The Secretary may by reg-
- 23 ulation impose restrictions on the advertising and
- promotion of a tobacco product consistent with and
- 25 to full extent permitted by the first amendment to

1	the Constitution. The finding as to whether such
2	regulation would be appropriate for the protection of
3	the public health shall be determined with respect to
4	the risks and benefits to the population as a whole,
5	including users and non-users of the tobacco prod-
6	uct, and taking into account—
7	"(A) the increased or decreased likelihood
8	that existing users of tobacco products will stop
9	using such products; and
10	"(B) the increased or decreased likelihood
11	that those who do not use tobacco products will
12	start using such products.
13	No such regulation may require that the sale or dis-
14	tribution of a tobacco product be limited to the writ-
15	ten or oral authorization of a practitioner licensed
16	by law to prescribe medical products.
17	"(2) Label Statements.—The label of a to-
18	bacco product shall bear such appropriate state-
19	ments of the restrictions required by a regulation
20	under subsection (a) as the Secretary may in such
21	regulation prescribe.
22	"(3) Limitations.—
23	"(A) In general.—No restrictions under
24	paragraph (1) may—

1	"(i) prohibit the sale of any tobacco	
2	product in face-to-face transactions by a	
3	specific category of retail outlets; or	
4	"(ii) establish a minimum age of sale	
5	of tobacco products to any person older	
6	than 18 years of age.	
7	"(B) MATCHBOOKS.—For purposes of any	
8	regulations issued by the Secretary, matchbooks	
9	of conventional size containing not more than	
10	20 paper matches, and which are customarily	
11	given away for free with the purchase of to-	
12	bacco products shall be considered as adult	
13	written publications which shall be permitted to	
14	contain advertising. Notwithstanding the pre-	
15	ceding sentence, if the Secretary finds that such	
16	treatment of matchbooks is not appropriate for	
17	the protection of the public health, the Sec-	
18	retary may determine by regulation that match-	
19	books shall not be considered adult written pub-	
20	lications.	
21	"(e) Good Manufacturing Practice Require-	
22	MENTS.—	
23	"(1) Methods, facilities, and controls to	
24	CONFORM.—	

"(A) IN GENERAL.—The Secretary may, in 1 2 accordance with subparagraph (B), prescribe regulations (which may differ based on the type 3 4 of tobacco product involved) requiring that the methods used in, and the facilities and controls 6 used for, the manufacture, pre-production de-7 sign validation (including a process to assess 8 the performance of a tobacco product), packing 9 and storage of a tobacco product, conform to 10 current good manufacturing practice, as prescribed in such regulations, to assure that the 12 public health is protected and that the tobacco 13 product is in compliance with this chapter. 14 Good manufacturing practices may include the 15 testing of raw tobacco for pesticide chemical 16 residues regardless of whether a tolerance for 17 such chemical residues has been established. 18

"(B) REQUIREMENTS.—The Secretary shall—

"(i) before promulgating any regulation under subparagraph (A), afford the Tobacco Products Scientific Advisory Committee an opportunity to submit recommendations with respect to the regulation proposed to be promulgated;

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1	"(ii) before promulgating any regula-
2	tion under subparagraph (A), afford oppor-
3	tunity for an oral hearing;
4	"(iii) provide the advisory committee a
5	reasonable time to make its recommenda-
6	tion with respect to proposed regulations
7	under subparagraph (A); and
8	"(iv) in establishing the effective date
9	of a regulation promulgated under this
10	subsection, take into account the dif-
11	ferences in the manner in which the dif-
12	ferent types of tobacco products have his-
13	torically been produced, the financial re-
14	sources of the different tobacco product
15	manufacturers, and the state of their exist-
16	ing manufacturing facilities, and shall pro-
17	vide for a reasonable period of time for
18	such manufacturers to conform to good
19	manufacturing practices.
20	"(2) Exemptions; variances.—
21	"(A) Petition.—Any person subject to
22	any requirement prescribed under paragraph
23	(1) may petition the Secretary for a permanent
24	or temporary exemption or variance from such

requirement. Such a petition shall be submitted

1	to the Secretary in such form and manner as
2	the Secretary shall prescribe and shall—
3	"(i) in the case of a petition for an ex-
4	emption from a requirement, set forth the
5	basis for the petitioner's determination
6	that compliance with the requirement is
7	not required to assure that the tobacco
8	product will be in compliance with this
9	chapter;
10	"(ii) in the case of a petition for a
11	variance from a requirement, set forth the
12	methods proposed to be used in, and the
13	facilities and controls proposed to be used
14	for, the manufacture, packing, and storage
15	of the tobacco product in lieu of the meth-
16	ods, facilities, and controls prescribed by
17	the requirement; and
18	"(iii) contain such other information
19	as the Secretary shall prescribe.
20	"(B) Referral to the tobacco prod-
21	UCTS SCIENTIFIC ADVISORY COMMITTEE.—The
22	Secretary may refer to the Tobacco Products
23	Scientific Advisory Committee any petition sub-
24	mitted under subparagraph (A). The Tobacco
25	Products Scientific Advisory Committee shall

1	report its recommendations to the Secretary
2	with respect to a petition referred to it within
3	60 days after the date of the petition's referral.
4	Within 60 days after—
5	"(i) the date the petition was sub-
6	mitted to the Secretary under subpara-
7	graph (A); or
8	"(ii) the day after the petition was re-
9	ferred to the Tobacco Products Scientific
10	Advisory Committee, whichever occurs
11	later, the Secretary shall by order either
12	deny the petition or approve it.
13	"(C) APPROVAL.—The Secretary may ap-
14	prove—
15	"(i) a petition for an exemption for a
16	tobacco product from a requirement if the
17	Secretary determines that compliance with
18	such requirement is not required to assure
19	that the tobacco product will be in compli-
20	ance with this chapter; and
21	"(ii) a petition for a variance for a to-
22	bacco product from a requirement if the
23	Secretary determines that the methods to
24	be used in, and the facilities and controls
25	to be used for, the manufacture, packing,

and storage of the tobacco product in lieu
of the methods, controls, and facilities prescribed by the requirement are sufficient to
assure that the tobacco product will be in
compliance with this chapter.

- "(D) CONDITIONS.—An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product to be granted the variance under the petition as may be necessary to assure that the tobacco product will be in compliance with this chapter.
- "(E) Hearing.—After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.
- "(3) COMPLIANCE.—Compliance with requirements under this subsection shall not be required before the period ending 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act.
- 24 "(f) Research and Development.—The Secretary 25 may enter into contracts for research, testing, and dem-

- 1 onstrations respecting tobacco products and may obtain
- 2 tobacco products for research, testing, and demonstration
- 3 purposes without regard to section 3324(a) and (b) of title
- 4 31, United States Code, and section 5 of title 41, United

"(1) Special rule for cigarettes.—A ciga-

5 States Code.

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6 "SEC. 907, TOBACCO PRODUCT STANDARDS.

- 7 "(a) IN GENERAL.—
- 9 rette or any of its component parts (including the 10 tobacco, filter, or paper) shall not contain, as a con-11 stituent (including a smoke constituent) or additive, 12 an artificial or natural flavor (other than tobacco or 13 menthol) or an herb or spice, including strawberry, 14 grape, orange, clove, cinnamon, pineapple, vanilla, 15 coconut, licorice, cocoa, chocolate, cherry, or coffee, 16 that is a characterizing flavor of the tobacco product 17 or tobacco smoke. Nothing in this subparagraph 18 shall be construed to limit the Secretary's authority 19 to take action under this section or other sections of 20 this Act applicable to menthol or any artificial or
- 23 "(2) REVISION OF TOBACCO PRODUCT STAND-24 ARDS.—The Secretary may revise the tobacco prod-

natural flavor, herb, or spice not specified in this

paragraph.

1	uct standards in paragraph (1) in accordance with
2	subsection (b).
3	"(3) Tobacco product standards.—The
4	Secretary may adopt tobacco product standards in
5	addition to those in paragraph (1) if the Secretary
6	finds that a tobacco product standard is appropriate
7	for the protection of the public health. This finding
8	shall be determined with respect to the risks and
9	benefits to the population as a whole, including
10	users and non-users of the tobacco product, and tak-
11	ing into account—
12	"(A) the increased or decreased likelihood
13	that existing users of tobacco products will stop
14	using such products; and
15	"(B) the increased or decreased likelihood
16	that those who do not use tobacco products will
17	start using such products.
18	"(4) Content of Tobacco Product Stand-
19	ARDS.—A tobacco product standard established
20	under this section for a tobacco product—
21	"(A) shall include provisions that are ap-
22	propriate for the protection of the public health,
23	including provisions, where appropriate—
24	"(i) for the reduction of nicotine
25	yields of the product;

1	"(ii) for the reduction or elimination
2	of other constituents, including smoke con-
3	stituents, or harmful components of the
4	product; or
5	"(iii) relating to any other require-
6	ment under (B);
7	"(B) shall, where appropriate for the pro-
8	tection of the public health, include—
9	"(i) provisions respecting the con-
10	struction, components, ingredients, addi-
11	tives, constituents, including smoke con-
12	stituents, and properties of the tobacco
13	product;
14	"(ii) provisions for the testing (on a
15	sample basis or, if necessary, on an indi-
16	vidual basis) of the tobacco product;
17	"(iii) provisions for the measurement
18	of the tobacco product characteristics of
19	the tobacco product;
20	"(iv) provisions requiring that the re-
21	sults of each or of certain of the tests of
22	the tobacco product required to be made
23	under clause (ii) show that the tobacco
24	product is in conformity with the portions

1	of the standard for which the test or tests
2	were required; and
3	"(v) a provision requiring that the
4	sale and distribution of the tobacco prod-
5	uct be restricted but only to the extent
6	that the sale and distribution of a tobacco
7	product may be restricted under a regula-
8	tion under section 906(d); and
9	"(C) shall, where appropriate, require the
10	use and prescribe the form and content of label-
11	ing for the proper use of the tobacco product.
12	"(5) Periodic re-evaluation of tobacco
13	PRODUCT STANDARDS.—The Secretary shall provide
14	for periodic evaluation of tobacco product standards
15	established under this section to determine whether
16	such standards should be changed to reflect new
17	medical, scientific, or other technological data. The
18	Secretary may provide for testing under paragraph
19	(4)(B) by any person.
20	"(6) Involvement of other agencies; in-
21	FORMED PERSONS.—In carrying out duties under
22	this section, the Secretary shall endeavor to—
23	"(A) use personnel, facilities, and other
24	technical support available in other Federal
25	agencies;

1	"(B) consult with other Federal agencies
2	concerned with standard-setting and other na-
3	tionally or internationally recognized standard-
4	setting entities; and
5	"(C) invite appropriate participation,
6	through joint or other conferences, workshops,
7	or other means, by informed persons represent-
8	ative of scientific, professional, industry, agri-
9	cultural, or consumer organizations who in the
10	Secretary's judgment can make a significant
11	contribution.
12	"(b) Establishment of Standards.—
13	"(1) Notice.—
14	"(A) IN GENERAL.—The Secretary shall
15	publish in the Federal Register a notice of pro-
16	posed rulemaking for the establishment, amend-
17	ment, or revocation of any tobacco product
18	standard.
19	"(B) Requirements of notice.—A no-
20	tice of proposed rulemaking for the establish-
21	ment or amendment of a tobacco product stand-
22	ard for a tobacco product shall—
23	"(i) set forth a finding with sup-
24	porting justification that the tobacco prod-

1	uct standard is appropriate for the protec-
2	tion of the public health;
3	"(ii) set forth proposed findings with
4	respect to the risk of illness or injury that
5	the tobacco product standard is intended
6	to reduce or eliminate; and
7	"(iii) invite interested persons to sub-
8	mit an existing tobacco product standard
9	for the tobacco product, including a draft
10	or proposed tobacco product standard, for
11	consideration by the Secretary.
12	"(C) Standard.—Upon a determination
13	by the Secretary that an additive, constituent
14	(including smoke constituent), or other compo-
15	nent of the product that is the subject of the
16	proposed tobacco product standard is harmful,
17	it shall be the burden of any party challenging
18	the proposed standard to prove that the pro-
19	posed standard will not reduce or eliminate the
20	risk of illness or injury.
21	"(D) FINDING.—A notice of proposed rule-
22	making for the revocation of a tobacco product
23	standard shall set forth a finding with sup-
24	porting justification that the tobacco product

standard is no longer appropriate for the protection of the public health.

"(E) Consideration by secretary.—
The Secretary shall consider all information submitted in connection with a proposed standard, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or non-tobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of such demand, and shall issue the standard if the Secretary determines that the standard would be appropriate for the protection of the public health.

"(F) COMMENT.—The Secretary shall provide for a comment period of not less than 60 days.

"(2) Promulgation.—

"(A) IN GENERAL.—After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a tobacco product standard and after consideration of such comments and any report

1	from the Tobacco Products Scientific Advisory
2	Committee, the Secretary shall—
3	"(i) promulgate a regulation estab-
4	lishing a tobacco product standard and
5	publish in the Federal Register findings on
6	the matters referred to in paragraph (1);
7	or
8	"(ii) publish a notice terminating the
9	proceeding for the development of the
10	standard together with the reasons for
11	such termination.
12	"(B) Effective date.—A regulation es-
13	tablishing a tobacco product standard shall set
14	forth the date or dates upon which the standard
15	shall take effect, but no such regulation may
16	take effect before 1 year after the date of its
17	publication unless the Secretary determines
18	that an earlier effective date is necessary for
19	the protection of the public health. Such date or
20	dates shall be established so as to minimize,
21	consistent with the public health, economic loss
22	to, and disruption or dislocation of, domestic
23	and international trade.
24	"(3) Power reserved to congress.—Be-
25	cause of the importance of a decision of the Sec-

1	retary to issue a regulation establishing a tobacco
2	product standard—
3	"(A) banning all cigarettes, all smokeless
4	tobacco products, all little cigars, all cigars
5	other than little cigars, all pipe tobacco, or all
6	roll your own tobacco products; or
7	"(B) requiring the reduction of nicotine
8	yields of a tobacco product to zero,
9	Congress expressly reserves to itself such power.
10	"(4) Amendment; revocation.—
11	"(A) AUTHORITY.—The Secretary, upon
12	the Secretary's own initiative or upon petition
13	of an interested person may by a regulation,
14	promulgated in accordance with the require-
15	ments of paragraphs (1) and (2)(B), amend or
16	revoke a tobacco product standard.
17	"(B) Effective date.—The Secretary
18	may declare a proposed amendment of a to-
19	bacco product standard to be effective on and
20	after its publication in the Federal Register and
21	until the effective date of any final action taken
22	on such amendment if the Secretary determines
23	that making it so effective is in the public inter-
24	est.

1	"(5) Reference to advisory committee.—
2	The Secretary may—

"(A) on the Secretary's own initiative, refer a proposed regulation for the establishment, amendment, or revocation of a tobacco product standard; or

"(B) upon the request of an interested person which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments on such proposed regulation, refer such proposed regulation to the Tobacco Products Scientific Advisory Committee, for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. If a proposed regulation is referred under this paragraph to the Tobacco Products Scientific Advisory Committee, the Secretary shall provide the advisory committee with the data and information on which such proposed regulation is based. The Tobacco Products Scientific Advisory Committee shall, within 60 days after the referral of a proposed regulation and after independent study of the data and information furnished to it by the Sec-

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retary and other data and information before it,
submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information
and a statement of the reason or basis for the
recommendation. A copy of such report and recommendation shall be made public by the Secretary.

9 "SEC. 908. NOTIFICATION AND OTHER REMEDIES.

- 10 "(a) Notification.—If the Secretary determines 11 that—
 - "(1) a tobacco product which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health; and
 - "(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk, the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all persons who should properly receive such notification in order to

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- 1 eliminate such risk. The Secretary may order notifi-
- 2 cation by any appropriate means, including public
- 3 service announcements. Before issuing an order
- 4 under this subsection, the Secretary shall consult
- 5 with the persons who are to give notice under the
- 6 order.
- 7 "(b) No Exemption From Other Liability.—
- 8 Compliance with an order issued under this section shall
- 9 not relieve any person from liability under Federal or
- 10 State law. In awarding damages for economic loss in an
- 11 action brought for the enforcement of any such liability,
- 12 the value to the plaintiff in such action of any remedy
- 13 provided under such order shall be taken into account.
- 14 "(c) Recall Authority.—
- 15 "(1) IN GENERAL.—If the Secretary finds that
- there is a reasonable probability that a tobacco prod-
- 17 uct contains a manufacturing or other defect not or-
- dinarily contained in tobacco products on the market
- that would cause serious, adverse health con-
- sequences or death, the Secretary shall issue an
- order requiring the appropriate person (including
- 22 the manufacturers, importers, distributors, or retail-
- ers of the tobacco product) to immediately cease dis-
- 24 tribution of such tobacco product. The order shall
- provide the person subject to the order with an op-

portunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such tobacco product. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

"(2) Amendment of order to require re-

"(A) IN GENERAL.—If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the tobacco product with respect to which the order was issued, the Secretary shall, except as provided in subparagraph (B), amend the order to require a recall. The Secretary shall specify a timetable in which the tobacco product recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

"(B) Notice.—An amended order under subparagraph (A)—

1	"(i) shall not include recall of a to-
2	bacco product from individuals; and
3	"(ii) shall provide for notice to per-
4	sons subject to the risks associated with
5	the use of such tobacco product.
6	In providing the notice required by clause (ii),
7	the Secretary may use the assistance of retail-
8	ers and other persons who distributed such to-
9	bacco product. If a significant number of such
10	persons cannot be identified, the Secretary shall
11	notify such persons under section 705(b).
12	"(3) Remedy not exclusive.—The remedy
13	provided by this subsection shall be in addition to
14	remedies provided by subsection (a) of this section.
15	"SEC. 909. RECORDS AND REPORTS ON TOBACCO PROD-
16	UCTS.
17	"(a) In General.—Every person who is a tobacco
18	product manufacturer or importer of a tobacco product
19	shall establish and maintain such records, make such re-
20	ports, and provide such information, as the Secretary may
21	by regulation reasonably require to assure that such to-
22	bacco product is not adulterated or misbranded and to
23	otherwise protect public health. Regulations prescribed
24	under the preceding sentence—

- 1 "(1) may require a tobacco product manufac-2 turer or importer to report to the Secretary when-3 ever the manufacturer or importer receives or otherwise becomes aware of information that reasonably 5 suggests that one of its marketed tobacco products 6 may have caused or contributed to a serious unex-7 pected adverse experience associated with the use of 8 the product or any significant increase in the fre-9 quency of a serious, expected adverse product experi-10 ence;
 - "(2) shall require reporting of other significant adverse tobacco product experiences as determined by the Secretary to be necessary to be reported;
 - "(3) shall not impose requirements unduly burdensome to a tobacco product manufacturer or importer, taking into account the cost of complying with such requirements and the need for the protection of the public health and the implementation of this chapter;
 - "(4) when prescribing the procedure for making requests for reports or information, shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request

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1	and identify to the fullest extent practicable such re-
2	port or information;
3	"(5) when requiring submission of a report or
4	information to the Secretary, shall state the reason
5	or purpose for the submission of such report or in-
6	formation and identify to the fullest extent prac-
7	ticable such report or information; and
8	"(6) may not require that the identity of any
9	patient or user be disclosed in records, reports, or
10	information required under this subsection unless re-
11	quired for the medical welfare of an individual, to
12	determine risks to public health of a tobacco prod-
13	uct, or to verify a record, report, or information sub-
14	mitted under this chapter.
15	In prescribing regulations under this subsection, the Sec-
16	retary shall have due regard for the professional ethics of
17	the medical profession and the interests of patients. The
18	prohibitions of paragraph (6) continue to apply to records,
19	reports, and information concerning any individual who
20	has been a patient, irrespective of whether or when he
21	ceases to be a patient.
22	"(b) Reports of Removals and Corrections.—
23	"(1) In general.—Except as provided in para-
24	graph (2), the Secretary shall by regulation require
25	a tobacco product manufacturer or importer of a to-

1	bacco product to report promptly to the Secretary
2	any corrective action taken or removal from the
3	market of a tobacco product undertaken by such
4	manufacturer or importer if the removal or correc-
5	tion was undertaken—
6	"(A) to reduce a risk to health posed by
7	the tobacco product; or
8	"(B) to remedy a violation of this chapter
9	caused by the tobacco product which may
10	present a risk to health.
11	A tobacco product manufacturer or importer of a to-
12	bacco product who undertakes a corrective action or
13	removal from the market of a tobacco product which
14	is not required to be reported under this subsection
15	shall keep a record of such correction or removal.
16	"(2) Exception.—No report of the corrective
17	action or removal of a tobacco product may be re-
18	quired under paragraph (1) if a report of the correc-
19	tive action or removal is required and has been sub-
20	mitted under subsection (a).
21	"SEC. 910. APPLICATION FOR REVIEW OF CERTAIN TO-
22	BACCO PRODUCTS.
23	"(a) In General —

1	"(1) New Tobacco Product Defined.—For
2	purposes of this section the term 'new tobacco prod-
3	uct' means—
4	"(A) any tobacco product (including those
5	products in test markets) that was not commer-
6	cially marketed in the United States as of June
7	1, 2003; or
8	"(B) any modification (including a change
9	in design, any component, any part, or any con-
10	stituent, including a smoke constituent, or in
11	the content, delivery or form of nicotine, or any
12	other additive or ingredient) of a tobacco prod-
13	uct where the modified product was commer-
14	cially marketed in the United States after June
15	1, 2003.
16	"(2) Premarket approval required.—
17	"(A) NEW PRODUCTS.—Approval under
18	this section of an application for premarket ap-
19	proval for any new tobacco product is required
20	unless—
21	"(i) the manufacturer has submitted a
22	report under section 905(j); and
23	"(ii) the Secretary has issued an order
24	that the tobacco product—

1	"(I) is substantially equivalent to
2	a tobacco product commercially mar-
3	keted (other than for test marketing)
4	in the United States as of June 1,
5	2003; and
6	"(II)(aa) is in compliance with
7	the requirements of this Act; or
8	"(bb) is exempt from the require-
9	ments of section 905(j) pursuant to a
10	regulation issued under section
11	905(j)(3).
12	"(B) Application to certain post
13	JUNE 1, 2003 PRODUCTS.—Subparagraph (A)
14	shall not apply to a tobacco product—
15	"(i) that was first introduced or deliv-
16	ered for introduction into interstate com-
17	merce for commercial distribution in the
18	United States after June 1, 2003, and
19	prior to the date that is 15 months after
20	the date of enactment of the Family Smok-
21	ing Prevention and Tobacco Control Act;
22	and
23	"(ii) for which a report was submitted
24	under section 905(j) within such 15-month
25	period, until the Secretary issues an order

1	that the tobacco product is not substan-
2	tially equivalent.
3	"(3) Substantially equivalent defined.—
4	"(A) IN GENERAL.—In this section and
5	section 905(j), the terms 'substantially equiva-
6	lent' or 'substantial equivalence' mean, with re-
7	spect to the tobacco product being compared to
8	the predicate tobacco product, that the Sec-
9	retary by order has found that the tobacco
10	product—
11	"(i) has the same characteristics as
12	the predicate tobacco product; or
13	"(ii) has different characteristics and
14	the information submitted contains infor-
15	mation, including clinical data if deemed
16	necessary by the Secretary, that dem-
17	onstrates that it is not appropriate to reg-
18	ulate the product under this section be-
19	cause the product does not raise different
20	questions of public health.
21	"(B) Characteristics.—In subpara-
22	graph (A), the term 'characteristics' means the
23	materials, ingredients, design, composition,
24	heating source, or other features of a tobacco
25	product.

"(C) LIMITATION.—A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

"(4) HEALTH INFORMATION.—

"(A) Summary.—As part of a submission under section 905(j) respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request by any person.

"(B) REQUIRED INFORMATION.—Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.

"(b) APPLICATION.—

1	"(1) Contents.—An application for premarket
2	approval shall contain—
3	"(A) full reports of all information, pub-
4	lished or known to, or which should reasonably
5	be known to, the applicant, concerning inves-
6	tigations which have been made to show the
7	health risks of such tobacco product and wheth-
8	er such tobacco product presents less risk than
9	other tobacco products;
10	"(B) a full statement of the components,
11	ingredients, additives, and properties, and of
12	the principle or principles of operation, of such
13	tobacco product;
14	"(C) a full description of the methods used
15	in, and the facilities and controls used for, the
16	manufacture, processing, and, when relevant,
17	packing and installation of, such tobacco prod-
18	uct;
19	"(D) an identifying reference to any to-
20	bacco product standard under section 907
21	which would be applicable to any aspect of such
22	tobacco product, and either adequate informa-
23	tion to show that such aspect of such tobacco
24	product fully meets such tobacco product stand-

1	ard or adequate information to justify any devi-
2	ation from such standard;
3	"(E) such samples of such to bacco product
4	and of components thereof as the Secretary
5	may reasonably require;
6	"(F) specimens of the labeling proposed to
7	be used for such tobacco product; and
8	"(G) such other information relevant to
9	the subject matter of the application as the Sec-
10	retary may require.
11	"(2) Reference to tobacco products sci-
12	ENTIFIC ADVISORY COMMITTEE.—Upon receipt of an
13	application meeting the requirements set forth in
14	paragraph (1), the Secretary—
15	"(A) may, on the Secretary's own initia-
16	tive; or
17	"(B) may, upon the request of an appli-
18	cant, refer such application to the Tobacco
19	Products Scientific Advisory Committee for ref-
20	erence and for submission (within such period
21	as the Secretary may establish) of a report and
22	recommendation respecting approval of the ap-
23	plication, together with all underlying data and
24	the reasons or basis for the recommendation.
25	"(c) ACTION ON APPLICATION.—

1	"(1) Deadline.—
2	"(A) In general.—As promptly as pos-
3	sible, but in no event later than 180 days after
4	the receipt of an application under subsection
5	(b), the Secretary, after considering the report
6	and recommendation submitted under para-
7	graph (2) of such subsection, shall—
8	"(i) issue an order approving the ap-
9	plication if the Secretary finds that none of
10	the grounds for denying approval specified
11	in paragraph (2) of this subsection applies;
12	or
13	"(ii) deny approval of the application
14	if the Secretary finds (and sets forth the
15	basis for such finding as part of or accom-
16	panying such denial) that 1 or more
17	grounds for denial specified in paragraph
18	(2) of this subsection apply.
19	"(B) RESTRICTIONS ON SALE AND DIS-
20	TRIBUTION.—An order approving an application
21	for a tobacco product may require as a condi-
22	tion to such approval that the sale and distribu-
23	tion of the tobacco product be restricted but
24	only to the extent that the sale and distribution

1	of a tobacco product may be restricted under a
2	regulation under section 906(d).
3	"(2) Denial of Approval.—The Secretary
4	shall deny approval of an application for a tobacco
5	product if, upon the basis of the information sub-
6	mitted to the Secretary as part of the application
7	and any other information before the Secretary with
8	respect to such tobacco product, the Secretary finds
9	that—
10	"(A) there is a lack of a showing that per-
11	mitting such tobacco product to be marketed
12	would be appropriate for the protection of the
13	public health;
14	"(B) the methods used in, or the facilities
15	or controls used for, the manufacture, proc-
16	essing, or packing of such tobacco product do
17	not conform to the requirements of section
18	906(e);
19	"(C) based on a fair evaluation of all mate-
20	rial facts, the proposed labeling is false or mis-
21	leading in any particular; or
22	"(D) such to bacco product is not shown to
23	conform in all respects to a tobacco product
24	standard in effect under section 907, compli-
25	ance with which is a condition to approval of

1	the application, and there is a lack of adequate
2	information to justify the deviation from such
3	standard.
4	"(3) DENIAL INFORMATION.—Any denial of an
5	application shall, insofar as the Secretary determines
6	to be practicable, be accompanied by a statement in-
7	forming the applicant of the measures required to
8	place such application in approvable form (which
9	measures may include further research by the appli-
10	cant in accordance with 1 or more protocols pre-
11	scribed by the Secretary).
12	"(4) Basis for finding.—For purposes of
13	this section, the finding as to whether approval of a
14	tobacco product is appropriate for the protection of
15	the public health shall be determined with respect to
16	the risks and benefits to the population as a whole
17	including users and nonusers of the tobacco product
18	and taking into account—
19	"(A) the increased or decreased likelihood
20	that existing users of tobacco products will stop
21	using such products; and
22	"(B) the increased or decreased likelihood
23	that those who do not use tobacco products will
24	start using such products.
25	"(5) Basis for action.—

"(A) Investigations.—For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may in-clude 1 or more clinical investigations by ex-perts qualified by training and experience to evaluate the tobacco product.

"(B) OTHER EVIDENCE.—If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product the Secretary may authorize that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.

"(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

"(1) IN GENERAL.—The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from an advisory committee, and after due notice and opportunity for informal hearing to the holder of an approved application for a tobacco product, issue an order withdrawing approval of the application if the Secretary finds—

1	"(A) that the continued marketing of such
2	tobacco product no longer is appropriate for the
3	protection of the public health;
4	"(B) that the application contained or was
5	accompanied by an untrue statement of a mate-
6	rial fact;
7	"(C) that the applicant—
8	"(i) has failed to establish a system
9	for maintaining records, or has repeatedly
10	or deliberately failed to maintain records
11	or to make reports, required by an applica-
12	ble regulation under section 909;
13	"(ii) has refused to permit access to,
14	or copying or verification of, such records
15	as required by section 704; or
16	"(iii) has not complied with the re-
17	quirements of section 905;
18	"(D) on the basis of new information be-
19	fore the Secretary with respect to such tobacco
20	product, evaluated together with the evidence
21	before the Secretary when the application was
22	approved, that the methods used in, or the fa-
23	cilities and controls used for, the manufacture,
24	processing, packing, or installation of such to-
25	bacco product do not conform with the require-

ments of section 906(e) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

"(E) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was approved, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

"(F) on the basis of new information before the Secretary, evaluated together with the
evidence before the Secretary when the application was approved, that such tobacco product is
not shown to conform in all respects to a tobacco product standard which is in effect under
section 907, compliance with which was a condition to approval of the application, and that
there is a lack of adequate information to justify the deviation from such standard.

"(2) APPEAL.—The holder of an application subject to an order issued under paragraph (1) with-

- drawing approval of the application may, by petition filed on or before the 30th day after the date upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with subsection (e).
- "(3) TEMPORARY SUSPENSION.—If, after pro-6 7 viding an opportunity for an informal hearing, the 8 Secretary determines there is reasonable probability 9 that the continuation of distribution of a tobacco 10 product under an approved application would cause 11 serious, adverse health consequences or death, that 12 is greater than ordinarily caused by tobacco prod-13 ucts on the market, the Secretary shall by order 14 temporarily suspend the approval of the application 15 approved under this section. If the Secretary issues 16 such an order, the Secretary shall proceed expedi-17 tiously under paragraph (1) to withdraw such appli-18 cation.
- 19 "(e) Service of Order.—An order issued by the20 Secretary under this section shall be served—
- 21 "(1) in person by any officer or employee of the 22 department designated by the Secretary; or
- 23 "(2) by mailing the order by registered mail or 24 certified mail addressed to the applicant at the ap-

plicant's last known address in the records of the Secretary.

"(f) Records.—

"(1) Additional information.—In the case of any tobacco product for which an approval of an application filed under subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, as the Secretary may by regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending such approval.

"(2) Access to Records.—Each person required under this section to maintain records, and each person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

23 "(g) Investigational Tobacco Product Exemp-24 tion for Investigational Use.—The Secretary may 25 exempt tobacco products intended for investigational use

1	from the provisions of this chapter under such conditions
2	as the Secretary may by regulation prescribe.
3	"SEC. 911. MODIFIED RISK TOBACCO PRODUCTS.
4	"(a) In General.—No person may introduce or de-
5	liver for introduction into interstate commerce any modi-
6	fied risk tobacco product unless approval of an application
7	filed pursuant to subsection (d) is effective with respect
8	to such product.
9	"(b) Definitions.—In this section:
10	"(1) Modified risk tobacco product.—The
11	term 'modified risk tobacco product' means any to-
12	bacco product that is sold or distributed for use to
13	reduce harm or the risk of tobacco-related disease
14	associated with commercially marketed tobacco prod-
15	ucts.
16	"(2) Sold or distributed.—
17	"(A) IN GENERAL.—With respect to a to-
18	bacco product, the term 'sold or distributed for
19	use to reduce harm or the risk of tobacco-re-
20	lated disease associated with commercially mar-
21	keted tobacco products' means a tobacco prod-
22	uet—
23	"(i) the label, labeling, or advertising
24	of which represents explicitly or implicitly
25	that—

1	"(I) the tobacco product presents
2	a lower risk of tobacco-related disease
3	or is less harmful than one or more
4	other commercially marketed tobacco
5	products;
6	" (II) the tobacco product or its
7	smoke contains a reduced level of a
8	substance or presents a reduced expo-
9	sure to a substance; or
10	"(III) the tobacco product or its
11	smoke does not contain or is free of a
12	substance;
13	"(ii) the label, labeling, or advertising
14	of which uses the descriptors 'light', 'mild',
15	or 'low' or similar descriptors; or
16	"(iii) the tobacco product manufac-
17	turer of which has taken any action di-
18	rected to consumers through the media or
19	otherwise, other than by means of the to-
20	bacco product's label, labeling or adver-
21	tising, after the date of enactment of the
22	Family Smoking Prevention and Tobacco
23	Control Act, respecting the product that
24	would be reasonably expected to result in
25	consumers believing that the tobacco prod-

1	uct or its smoke may present a lower risk
2	of disease or is less harmful than one or
3	more commercially marketed tobacco prod-
4	ucts, or presents a reduced exposure to, or
5	does not contain or is free of, a substance
6	or substances.
7	"(B) Limitation.—No tobacco product
8	shall be considered to be 'sold or distributed for
9	use to reduce harm or the risk of tobacco-re-
10	lated disease associated with commercially mar-
11	keted tobacco products', except as described in
12	subparagraph (A).
13	"(c) Tobacco Dependence Products.—A product
14	that is intended to be used for the treatment of tobacco
15	dependence, including smoking cessation, is not a modified
16	risk tobacco product under this section and is subject to
17	the requirements of chapter V.
18	"(d) FILING.—Any person may file with the Sec-
19	retary an application for a modified risk tobacco product.
20	Such application shall include—
21	"(1) a description of the proposed product and
22	any proposed advertising and labeling;
23	"(2) the conditions for using the product;
24	"(3) the formulation of the product;
25	"(4) sample product labels and labeling;

1	"(5) all documents (including underlying sci-
2	entific information) relating to research findings
3	conducted, supported, or possessed by the tobacco
4	product manufacturer relating to the effect of the
5	product on tobacco-related diseases and health-re-
6	lated conditions, including information both favor-
7	able and unfavorable to the ability of the product to
8	reduce risk or exposure and relating to human
9	health;
10	"(6) data and information on how consumers
11	actually use the tobacco product; and
12	"(7) such other information as the Secretary
13	may require.
14	"(e) Public Availability.—The Secretary shall
15	make the application described in subsection (d) publicly
16	available (except matters in the application which are
17	trade secrets or otherwise confidential, commercial infor-
18	mation) and shall request comments by interested persons
19	on the information contained in the application and on the
20	label, labeling, and advertising accompanying such appli-
21	cation.
22	"(f) Advisory Committee.—
23	"(1) IN GENERAL.—The Secretary shall refer to
24	an advisory committee any application submitted
25	under this subsection.

1	"(2) RECOMMENDATIONS.—Not later than 60
2	days after the date an application is referred to an
3	advisory committee under paragraph (1), the advi-
4	sory committee shall report its recommendations on
5	the application to the Secretary.
6	"(g) Approval.—
7	"(1) Modified risk products.—Except as
8	provided in paragraph (2), the Secretary shall ap-
9	prove an application for a modified risk tobacco
10	product filed under this section only if the Secretary
11	determines that the applicant has demonstrated that
12	such product, as it is actually used by consumers,
13	will—
14	"(A) significantly reduce harm and the
15	risk of tobacco-related disease to individual to-
16	bacco users; and
17	"(B) benefit the health of the population
18	as a whole taking into account both users of to-
19	bacco products and persons who do not cur-
20	rently use tobacco products.
21	"(2) Special rule for certain products.—
22	"(A) IN GENERAL.—The Secretary may
23	approve an application for a tobacco product
24	that has not been approved as a modified risk
25	tobacco product pursuant to paragraph (1) if

1 the Secretary makes	the findings required
2 under this paragraph an	nd determines that the
3 applicant has demonstrate	ted that—
4 "(i) the appro	oval of the application
5 would be appropriat	ce to promote the public
6 health;	
7 "(ii) any aspec	et of the label, labeling,
8 and advertising for	or such product that
9 would cause the to	bacco product to be a
10 modified risk tobac	eco product under sub-
section (b)(2) is $\lim_{x \to 0} x = 1$	mited to an explicit or
implicit representat	tion that such tobacco
product or its smok	ce contains or is free of
a substance or cont	tains a reduced level of
a substance, or pre	esents a reduced expo-
sure to a substance	in tobacco smoke;
17 "(iii) scientific	evidence is not avail-
able and, using the	best available scientific
methods, cannot be	made available without
20 conducting long-term	m epidemiological stud-
ies for an applicati	ion to meet the stand-
ards set forth in par	ragraph (1); and
23 "(iv) the scien	ntific evidence that is
24 available without co	nducting long-term epi-
25 demiological studies	s demonstrates that a

1	measurable and substantial reduction in
2	morbidity or mortality among individual
3	tobacco users is anticipated in subsequent
4	studies.
5	"(B) Additional findings required.—
6	In order to approve an application under sub-
7	paragraph (A) the Secretary must also find
8	that the applicant has demonstrated that—
9	"(i) the magnitude of the overall re-
10	ductions in exposure to the substance or
11	substances which are the subject of the ap-
12	plication is substantial, such substance or
13	substances are harmful, and the product as
14	actually used exposes consumers to the
15	specified reduced level of the substance or
16	substances;
17	"(ii) the product as actually used by
18	consumers will not expose them to higher
19	levels of other harmful substances com-
20	pared to the similar types of tobacco prod-
21	ucts then on the market unless such in-
22	creases are minimal and the anticipated
23	overall impact of use of the product re-
24	mains a substantial and measurable reduc-

1	tion in overall morbidity and mortality
2	among individual tobacco users;
3	"(iii) testing of actual consumer per-
4	ception shows that, as the applicant pro-
5	poses to label and market the product, con-
6	sumers will not be misled into believing
7	that the product—
8	"(I) is or has been demonstrated
9	to be less harmful; or
10	"(II) presents or has been dem-
11	onstrated to present less of a risk of
12	disease than 1 or more other commer-
13	cially marketed tobacco products; and
14	"(iv) approval of the application is ex-
15	pected to benefit the health of the popu-
16	lation as a whole taking into account both
17	users of tobacco products and persons who
18	do not currently use tobacco products.
19	"(C) CONDITIONS OF APPROVAL.—
20	"(i) In general.—Applications ap-
21	proved under this paragraph shall be lim-
22	ited to a term of not more than 5 years,
23	but may be renewed upon a finding by the
24	Secretary that the requirements of this

1	paragraph continue to be satisfied based
2	on the filing of a new application.
3	"(ii) Agreements by applicant.—
4	Applications approved under this para-
5	graph shall be conditioned on the appli-
6	cant's agreement to conduct post-market
7	surveillance and studies and to submit to
8	the Secretary the results of such surveil-
9	lance and studies to determine the impact
10	of the application approval on consumer
11	perception, behavior, and health and to en-
12	able the Secretary to review the accuracy
13	of the determinations upon which the ap-
14	proval was based in accordance with a pro-
15	tocol approved by the Secretary.
16	"(iii) Annual submission.—The re-
17	sults of such post-market surveillance and
18	studies described in clause (ii) shall be
19	submitted annually.
20	"(3) Basis.—The determinations under para-
21	graphs (1) and (2) shall be based on—
22	"(A) the scientific evidence submitted by
23	the applicant; and
24	"(B) scientific evidence and other informa-
25	tion that is available to the Secretary.

1	"(4) Benefit to health of individuals
2	AND OF POPULATION AS A WHOLE.—In making the
3	determinations under paragraphs (1) and (2), the
4	Secretary shall take into account—
5	"(A) the relative health risks to individuals
6	of the tobacco product that is the subject of the
7	application;
8	"(B) the increased or decreased likelihood
9	that existing users of tobacco products who
10	would otherwise stop using such products will
11	switch to the tobacco product that is the subject
12	of the application;
13	"(C) the increased or decreased likelihood
14	that persons who do not use tobacco products
15	will start using the tobacco product that is the
16	subject of the application;
17	"(D) the risks and benefits to persons
18	from the use of the tobacco product that is the
19	subject of the application as compared to the
20	use of products for smoking cessation approved
21	under chapter V to treat nicotine dependence;
22	and
23	"(E) comments, data, and information
24	submitted by interested persons.
25	"(h) Additional Conditions for Approval.—

"(1) Modified risk products.—The Secretary shall require for the approval of an application under this section that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products.

"(2) Comparative claims.—

"(A) IN GENERAL.—The Secretary may require for the approval of an application under this subsection that a claim comparing a to-bacco product to 1 or more other commercially marketed tobacco products shall compare the tobacco product to a commercially marketed tobacco product that is representative of that type of tobacco product on the market (for example the average value of the top 3 brands of an established regular tobacco product).

"(B) QUANTITATIVE COMPARISONS.—The Secretary may also require, for purposes of subparagraph (A), that the percent (or fraction) of change and identity of the reference tobacco product and a quantitative comparison of the amount of the substance claimed to be reduced shall be stated in immediate proximity to the most prominent claim.

"(3) Label disclosure.—

- "(A) IN GENERAL.—The Secretary may require the disclosure on the label of other substances in the tobacco product, or substances that may be produced by the consumption of that tobacco product, that may affect a disease or health-related condition or may increase the risk of other diseases or health-related conditions associated with the use of tobacco products.
- "(B) CONDITIONS OF USE.—If the conditions of use of the tobacco product may affect the risk of the product to human health, the Secretary may require the labeling of conditions of use.
- "(4) TIME.—The Secretary shall limit an approval under subsection (g)(1) for a specified period of time.
- "(5) ADVERTISING.—The Secretary may require that an applicant, whose application has been approved under this subsection, comply with require-

1 ments relating to advertising and promotion of the 2 tobacco product.

"(i) Postmarket Surveillance and Studies.—

"(1) IN GENERAL.—The Secretary shall require that an applicant under subsection (g)(1) conduct post market surveillance and studies for a tobacco product for which an application has been approved to determine the impact of the application approval on consumer perception, behavior, and health, to enable the Secretary to review the accuracy of the determinations upon which the approval was based, and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product. The results of post-market surveillance and studies shall be submitted to the Secretary on an annual basis.

"(2) Surveillance protocol.—Each applicant required to conduct a surveillance of a tobacco product under paragraph (1) shall, within 30 days after receiving notice that the applicant is required to conduct such surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance. The Secretary, within 60 days of the receipt of such protocol, shall determine if the principal investigator proposed to be used in the surveil-

1	lance has sufficient qualifications and experience to
2	conduct such surveillance and if such protocol will
3	result in collection of the data or other information
4	designated by the Secretary as necessary to protect
5	the public health.
6	"(j) Withdrawal of Approval.—The Secretary,
7	after an opportunity for an informal hearing, shall with-
8	draw the approval of an application under this section if
9	the Secretary determines that—
10	"(1) the applicant, based on new information,
11	can no longer make the demonstrations required
12	under subsection (g), or the Secretary can no longer
13	make the determinations required under subsection
14	(g);
15	"(2) the application failed to include material
16	information or included any untrue statement of ma-
17	terial fact;
18	"(3) any explicit or implicit representation that
19	the product reduces risk or exposure is no longer
20	valid, including if—
21	"(A) a tobacco product standard is estab-
22	lished pursuant to section 907;
23	"(B) an action is taken that affects the
24	risks presented by other commercially marketed

1	tobacco products that were compared to the
2	product that is the subject of the application; or
3	"(C) any postmarket surveillance or stud-
4	ies reveal that the approval of the application is
5	no longer consistent with the protection of the
6	public health;
7	"(4) the applicant failed to conduct or submit
8	the postmarket surveillance and studies required
9	under subsection (g)(2)(C)(ii) or (i); or
10	"(5) the applicant failed to meet a condition
11	imposed under subsection (h).
12	"(k) Chapter IV or V.—A product approved in ac-
13	cordance with this section shall not be subject to chapter
14	IV or V.
15	"(l) Implementing Regulations or Guidance.—
16	"(1) Scientific evidence.—Not later than 2
17	years after the date of enactment of the Family
18	Smoking Prevention and Tobacco Control Act, the
19	Secretary shall issue regulations or guidance (or any
20	combination thereof) on the scientific evidence re-
21	quired for assessment and ongoing review of modi-
22	fied risk tobacco products. Such regulations or guid-
23	ance shall—
24	"(A) establish minimum standards for sci-
25	entific studies needed prior to approval to show

1	that a substantial reduction in morbidity or
2	mortality among individual tobacco users is
3	likely;
4	"(B) include validated biomarkers, inter-
5	mediate clinical endpoints, and other feasible
6	outcome measures, as appropriate;
7	"(C) establish minimum standards for post
8	market studies, that shall include regular and
9	long-term assessments of health outcomes and
10	mortality, intermediate clinical endpoints, con-
11	sumer perception of harm reduction, and the
12	impact on quitting behavior and new use of to-
13	bacco products, as appropriate;
14	"(D) establish minimum standards for re-
15	quired postmarket surveillance, including ongo-
16	ing assessments of consumer perception; and
17	"(E) require that data from the required
18	studies and surveillance be made available to
19	the Secretary prior to the decision on renewal
20	of a modified risk tobacco product.
21	"(2) Consultation.—The regulations or guid-
22	ance issued under paragraph (1) shall be developed
23	in consultation with the Institute of Medicine, and
24	with the input of other appropriate scientific and

- medical experts, on the design and conduct of such
 studies and surveillance.
- "(3) REVISION.—The regulations or guidance under paragraph (1) shall be revised on a regular basis as new scientific information becomes available.
- "(4) New Tobacco Products.—Not later 7 8 than 2 years after the date of enactment of the 9 Family Smoking Prevention and Tobacco Control 10 Act, the Secretary shall issue a regulation or guid-11 ance that permits the filing of a single application 12 for any tobacco product that is a new tobacco prod-13 uct under section 910 and for which the applicant 14 seeks approval as a modified risk tobacco product 15 under this section.
- action, after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, with respect to a tobacco product that would reasonably be expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco prod-

ucts, or presents a reduced exposure to, or does not con-

"(m) DISTRIBUTORS.—No distributor may take any

1 "SEC. 912. JUDICIAL REVIEW.

2	"(a) Right to Review.—
3	"(1) In General.—Not later than 30 days
4	after—
5	"(A) the promulgation of a regulation
6	under section 907 establishing, amending, or
7	revoking a tobacco product standard; or
8	"(B) a denial of an application for ap-
9	proval under section 910(c), any person ad-
10	versely affected by such regulation or denial
11	may file a petition for judicial review of such
12	regulation or denial with the United States
13	Court of Appeals for the District of Columbia
14	or for the circuit in which such person resides
15	or has their principal place of business.
16	"(2) Requirements.—
17	"(A) COPY OF PETITION.—A copy of the
18	petition filed under paragraph (1) shall be
19	transmitted by the clerk of the court involved to
20	the Secretary.
21	"(B) RECORD OF PROCEEDINGS.—On re-
22	ceipt of a petition under subparagraph (A), the
23	Secretary shall file in the court in which such
24	petition was filed—

1	"(i) the record of the proceedings on
2	which the regulation or order was based;
3	and
4	"(ii) a statement of the reasons for
5	the issuance of such a regulation or order.
6	"(C) Definition of Record.—In this
7	section, the term 'record' means—
8	"(i) all notices and other matter pub-
9	lished in the Federal Register with respect
10	to the regulation or order reviewed;
11	"(ii) all information submitted to the
12	Secretary with respect to such regulation
13	or order;
14	"(iii) proceedings of any panel or ad-
15	visory committee with respect to such reg-
16	ulation or order;
17	"(iv) any hearing held with respect to
18	such regulation or order; and
19	"(v) any other information identified
20	by the Secretary, in the administrative pro-
21	ceeding held with respect to such regula-
22	tion or order, as being relevant to such
23	regulation or order.
24	"(b) STANDARD OF REVIEW.—Upon the filing of the
25	petition under subsection (a) for judicial review of a regu-

- 1 lation or order, the court shall have jurisdiction to review
- 2 the regulation or order in accordance with chapter 7 of
- 3 title 5, United States Code, and to grant appropriate re-
- 4 lief, including interim relief, as provided for in such chap-
- 5 ter. A regulation or denial described in subsection (a) shall
- 6 be reviewed in accordance with section 706(2)(A) of title
- 7 5, United States Code.
- 8 "(c) Finality of Judgment.—The judgment of the
- 9 court affirming or setting aside, in whole or in part, any
- 10 regulation or order shall be final, subject to review by the
- 11 Supreme Court of the United States upon certiorari or
- 12 certification, as provided in section 1254 of title 28,
- 13 United States Code.
- 14 "(d) Other Remedies.—The remedies provided for
- 15 in this section shall be in addition to, and not in lieu of,
- 16 any other remedies provided by law.
- 17 "(e) Regulations and Orders Must Recite
- 18 Basis in Record.—To facilitate judicial review, a regula-
- 19 tion or order issued under section 906, 907, 908, 909,
- 20 910, or 916 shall contain a statement of the reasons for
- 21 the issuance of such regulation or order in the record of
- 22 the proceedings held in connection with its issuance.
- 23 "SEC. 913. EQUAL TREATMENT OF RETAIL OUTLETS.
- 24 "The Secretary shall issue regulations to require that
- 25 retail establishments for which the predominant business

is the sale of tobacco products comply with any advertising restrictions applicable to retail establishments accessible 3 to individuals under the age of 18. 4 "SEC. 914. JURISDICTION OF AND COORDINATION WITH 5 THE FEDERAL TRADE COMMISSION. 6 "(a) Jurisdiction.— 7 "(1) In General.—Except where expressly 8 provided in this chapter, nothing in this chapter 9 shall be construed as limiting or diminishing the au-10 thority of the Federal Trade Commission to enforce 11 the laws under its jurisdiction with respect to the 12 advertising, sale, or distribution of tobacco products. "(2) Enforcement.—Any advertising that vio-13 14 lates this chapter or a provision of the regulations 15 referred to in section 232 of the Family Smoking 16 Prevention and Tobacco Control Act, is an unfair or 17 deceptive act or practice under section 5(a) of the 18 Federal Trade Commission Act (15 U.S.C. 45(a)) 19 and shall be considered a violation of a rule promul-20 gated under section 18 of that Act (15 U.S.C. 57a). 21 "(b) Coordination.—With respect to the requirements of section 4 of the Federal Cigarette Labeling and 23 Advertising Act (15 U.S.C. 1333) and section 3 of the Comprehensive Smokeless Tobacco Health Education Act

of 1986 (15 U.S.C. 4402)—

- 1 "(1) the Chairman of the Federal Trade Com-
- 2 mission shall coordinate with the Secretary con-
- 3 cerning the enforcement of such Act as such enforce-
- 4 ment relates to unfair or deceptive acts or practices
- 5 in the advertising of cigarettes or smokeless tobacco;
- 6 and
- 7 "(2) the Secretary shall consult with the Chair-
- 8 man of such Commission in revising the label state-
- 9 ments and requirements under such sections.

10 "SEC. 915. CONGRESSIONAL REVIEW PROVISIONS.

- "In accordance with section 801 of title 5, United
- 12 States Code, Congress shall review, and may disapprove,
- 13 any rule under this chapter that is subject to section 801.
- 14 This section and section 801 do not apply to the regula-
- 15 tions referred to in section 232 of the Family Smoking
- 16 Prevention and Tobacco Control Act.

17 "SEC. 916. REGULATION REQUIREMENT.

- 18 "(a) Testing, Reporting, and Disclosure.—Not
- 19 later than 24 months after the date of enactment of the
- 20 Family Smoking Prevention and Tobacco Control Act, the
- 21 Secretary, acting through the Commissioner of the Food
- 22 and Drug Administration, shall promulgate regulations
- 23 under this Act that meet the requirements of subsection
- 24 (b).

1	"(b) Contents of Rules.—The regulations pro-
2	mulgated under subsection (a) shall require testing and
3	reporting of tobacco product constituents, ingredients, and
4	additives, including smoke constituents, by brand and sub-
5	brand that the Secretary determines should be tested to
6	protect the public health. The regulations may require
7	that tobacco product manufacturers, packagers, or import-
8	ers make disclosures relating to the results of the testing
9	of tar and nicotine through labels or advertising or other
10	appropriate means, and make disclosures regarding the re-
11	sults of the testing of other constituents, including smoke
12	constituents, ingredients, or additives, that the Secretary
13	determines should be disclosed to the public to protect the
14	public health and will not mislead consumers about the
15	risk of tobacco related disease.
16	"(c) Authority.—The Food and Drug Administra-
17	tion shall have the authority under this chapter to conduct
18	or to require the testing, reporting, or disclosure of to-
19	bacco product constituents, including smoke constituents.
20	"SEC. 917. PRESERVATION OF STATE AND LOCAL AUTHOR-
21	ITY.
22	"(a) In General.—
23	"(1) Preservation.—Nothing in this chapter,
24	or rules promulgated under this chapter, shall be
25	construed to limit the authority of a Federal agency

(including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this chapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products. No provision of this chapter shall limit or otherwise affect any State, Tribal, or local taxation of tobacco products.

"(2) Preemption of Certain State and Local requirements.—

"(A) IN GENERAL.—Except as provided in paragraph (1) and subparagraph (B), no State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to tobacco product standards, premarket approval,

adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

- does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products. Information disclosed to a State under subparagraph (A) that is exempt from disclosure under section 554(b)(4) of title 5, United States Code, shall be treated as trade secret and confidential information by the State.
- "(b) Rule of Construction Regarding Product
 Liability.—No provision of this chapter relating to a tobacco product shall be construed to modify or otherwise
 affect any action or the liability of any person under the
 product liability law of any State.

21 "SEC. 918. TOBACCO PRODUCTS SCIENTIFIC ADVISORY 22 COMMITTEE.

"(a) ESTABLISHMENT.—Not later than 1 year after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish an

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1	11-member advisory committee, to be known as the 'To
2	bacco Products Scientific Advisory Committee'.
3	"(b) Membership.—
4	"(1) In general.—
5	"(A) Members.—The Secretary shall ap
6	point as members of the Tobacco Products Sci
7	entific Advisory Committee individuals who are
8	technically qualified by training and experience
9	in the medicine, medical ethics, science, or tech
10	nology involving the manufacture, evaluation, or
11	use of tobacco products, who are of appro
12	priately diversified professional backgrounds
13	The committee shall be composed of—
14	"(i) 7 individuals who are physicians
15	dentists, scientists, or health care profes
16	sionals practicing in the area of oncology
17	pulmonology, cardiology, toxicology, phar
18	macology, addiction, or any other relevant
19	specialty;
20	"(ii) 1 individual who is an officer of
21	employee of a State or local government or
22	of the Federal Government;
23	"(iii) 1 individual as a representative
24	of the general public;

1	"(iv) 1 individual as a representative
2	of the interests in the tobacco manufac-
3	turing industry; and
4	"(v) 1 individual as a representative
5	of the interests of the tobacco growers.
6	"(B) Nonvoting members.—The mem-
7	bers of the committee appointed under clauses
8	(iv) and (v) of subparagraph (A) shall serve as
9	consultants to those described in clauses (i)
10	through (iii) of subparagraph (A) and shall be
11	nonvoting representatives.
12	"(2) Limitation.—The Secretary may not ap-
13	point to the Advisory Committee any individual who
14	is in the regular full-time employ of the Food and
15	Drug Administration or any agency responsible for
16	the enforcement of this Act. The Secretary may ap-
17	point Federal officials as ex officio members.
18	"(3) Chairperson.—The Secretary shall des-
19	ignate 1 of the members of the Advisory Committee
20	to serve as chairperson.
21	"(c) Duties.—The Tobacco Products Scientific Ad-
22	visory Committee shall provide advice, information, and
23	recommendations to the Secretary—
24	"(1) as provided in this chapter:

- 1 "(2) on the effects of the alteration of the nico-2 tine yields from tobacco products;
- 3 "(3) on whether there is a threshold level below 4 which nicotine yields do not produce dependence on 5 the tobacco product involved; and
 - "(4) on its review of other safety, dependence, or health issues relating to tobacco products as requested by the Secretary.

"(d) Compensation; Support; FACA.—

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"(1) Compensation and Travel.—Members of the Advisory Committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which may not exceed the daily equivalent of the rate in effect for level 4 of the Senior Executive Schedule under section 5382 of title 5, United States Code, for each day (including travel time) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

1	"(2) Administrative support.—The Sec-
2	retary shall furnish the Advisory Committee clerical
3	and other assistance.
4	"(3) Nonapplication of faca.—Section 14 of
5	the Federal Advisory Committee Act (5 U.S.C.
6	App.) does not apply to the Advisory Committee.
7	"(e) Proceedings of Advisory Panels and Com-
8	MITTEES.—The Advisory Committee shall make and
9	maintain a transcript of any proceeding of the panel or
10	committee. Each such panel and committee shall delete
11	from any transcript made under this subsection informa-
12	tion which is exempt from disclosure under section 552(b)
13	of title 5, United States Code.
13 14	of title 5, United States Code. "SEC. 919. DRUG PRODUCTS USED TO TREAT TOBACCO DE-
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14	"SEC. 919. DRUG PRODUCTS USED TO TREAT TOBACCO DE-
14 15	"SEC. 919. DRUG PRODUCTS USED TO TREAT TOBACCO DE- PENDENCE.
14 15 16	"SEC. 919. DRUG PRODUCTS USED TO TREAT TOBACCO DE- PENDENCE. "The Secretary shall—
14 15 16 17	"SEC. 919. DRUG PRODUCTS USED TO TREAT TOBACCO DE- PENDENCE. "The Secretary shall— "(1) at the request of the applicant, consider
14 15 16 17 18	"SEC. 919. DRUG PRODUCTS USED TO TREAT TOBACCO DE- PENDENCE. "The Secretary shall— "(1) at the request of the applicant, consider designating nicotine replacement products as fast
14 15 16 17 18	"SEC. 919. DRUG PRODUCTS USED TO TREAT TOBACCO DE- PENDENCE. "The Secretary shall— "(1) at the request of the applicant, consider designating nicotine replacement products as fast track research and approval products within the
14 15 16 17 18 19 20	"SEC. 919. DRUG PRODUCTS USED TO TREAT TOBACCO DE- PENDENCE. "The Secretary shall— "(1) at the request of the applicant, consider designating nicotine replacement products as fast track research and approval products within the meaning of section 506;
14 15 16 17 18 19 20 21	"SEC. 919. DRUG PRODUCTS USED TO TREAT TOBACCO DE- PENDENCE. "The Secretary shall— "(1) at the request of the applicant, consider designating nicotine replacement products as fast track research and approval products within the meaning of section 506; "(2) consider approving the extended use of nic-

1	"(3) review and consider the evidence for addi-
2	tional indications for nicotine replacement products,
3	such as for craving relief or relapse prevention.
4	"SEC. 920. USER FEE.
5	"(a) Establishment of Quarterly User Fee.—
6	The Secretary shall assess a quarterly user fee with re-
7	spect to every quarter of each fiscal year commencing fis-
8	cal year 2007, calculated in accordance with this section,
9	upon each manufacturer and importer of tobacco products
10	subject to this chapter.
11	"(b) Funding of FDA Regulation of Tobacco
12	PRODUCTS.—The Secretary shall make user fees collected
13	pursuant to this section available to pay, in each fiscal
14	year, for the costs of the activities of the Food and Drug
15	Administration related to the regulation of tobacco prod-
16	ucts under this chapter.
17	"(c) Assessment of User Fee.—
18	"(1) Amount of assessment.—Except as
19	provided in paragraph (4), the total user fees as-
20	sessed each year pursuant to this section shall be
21	sufficient, and shall not exceed what is necessary, to
22	pay for the costs of the activities described in sub-
23	section (b) for each fiscal year.
24	"(2) Allocation of assessment by class
25	OF TOBACCO PRODUCTS.—

1	"(A) In General.—Subject to paragraph
2	(3), the total user fees assessed each fiscal year
3	with respect to each class of importers and
4	manufacturers shall be equal to an amount that
5	is the applicable percentage of the total costs of
6	activities of the Food and Drug Administration
7	described in subsection (b).
8	"(B) APPLICABLE PERCENTAGE.—For
9	purposes of subparagraph (A) the applicable
10	percentage for a fiscal year shall be the fol-
11	lowing:
12	"(i) 92.07 percent shall be assessed
13	on manufacturers and importers of ciga-
14	rettes;
15	"(ii) 0.05 percent shall be assessed on
16	manufacturers and importers of little ci-
17	gars;
18	"(iii) 7.15 percent shall be assessed
19	on manufacturers and importers of cigars
20	other than little cigars;
21	"(iv) 0.43 percent shall be assessed on
22	manufacturers and importers of snuff;
23	"(v) 0.10 percent shall be assessed on
24	manufacturers and importers of chewing
25	tobacco;

1	"(vi) 0.06 percent shall be assessed on
2	manufacturers and importers of pipe to-
3	bacco; and
4	"(vii) 0.14 percent shall be assessed
5	on manufacturers and importers of roll-
6	your-own tobacco.
7	"(3) Distribution of fee shares of manu-
8	FACTURERS AND IMPORTERS EXEMPT FROM USER
9	FEE.—Where a class of tobacco products is not sub-
10	ject to a user fee under this section, the portion of
11	the user fee assigned to such class under subsection
12	(d)(2) shall be allocated by the Secretary on a pro-
13	rata basis among the classes of tobacco products
14	that are subject to a user fee under this section.
15	Such pro rata allocation for each class of tobacco
16	products that are subject to a user fee under this
17	section shall be the quotient of—
18	"(A) the sum of the percentages assigned
19	to all classes of tobacco products subject to this
20	section; divided by
21	"(B) the percentage assigned to such class
22	under paragraph (2).
23	"(4) Annual Limit on assessment.—The
24	total assessment under this section—

1	"(A) for fiscal year 2007 shall be
2	\$85,000,000;
3	"(B) for fiscal year 2008 shall be
4	\$175,000,000;
5	"(C) for fiscal year 2009 shall be
6	\$300,000,000; and
7	"(D) for each subsequent fiscal year, shall
8	not exceed the limit on the assessment imposed
9	during the previous fiscal year, as adjusted by
10	the Secretary (after notice, published in the
11	Federal Register) to reflect the greater of—
12	"(i) the total percentage change that
13	occurred in the Consumer Price Index for
14	all urban consumers (all items; United
15	States city average) for the 12-month pe-
16	riod ending on June 30 of the preceding
17	fiscal year for which fees are being estab-
18	lished; or
19	"(ii) the total percentage change for
20	the previous fiscal year in basic pay under
21	the General Schedule in accordance with
22	section 5332 of title 5, United States
23	Code, as adjusted by any locality-based
24	comparability payment pursuant to section

1	5304 of such title for Federal employees
2	stationed in the District of Columbia.
3	"(5) Timing of user fee assessment.—The
4	Secretary shall notify each manufacturer and im-
5	porter of tobacco products subject to this section of
6	the amount of the quarterly assessment imposed or
7	such manufacturer or importer under subsection (f
8	during each quarter of each fiscal year. Such notifi-
9	cations shall occur not earlier than 3 months prior
10	to the end of the quarter for which such assessment
11	is made, and payments of all assessments shall be
12	made not later than 60 days after each such notifi-
13	eation.
14	"(d) Determination of User Fee by Company
15	Market Share.—
16	"(1) IN GENERAL.—The user fee to be paid by
17	each manufacturer or importer of a given class of to-
18	bacco products shall be determined in each quarter
19	by multiplying—
20	"(A) such manufacturer's or importer's
21	market share of such class of tobacco products
22	by
23	"(B) the portion of the user fee amount
24	for the current quarter to be assessed on manu-

1	facturers and importers of such class of tobacco
2	products as determined under subsection (e).
3	"(2) No fee in excess of market share.—
4	No manufacturer or importer of tobacco products
5	shall be required to pay a user fee in excess of the
6	market share of such manufacturer or importer.
7	"(e) Determination of Volume of Domestic
8	Sales.—
9	"(1) In general.—The calculation of gross
10	domestic volume of a class of tobacco product by a
11	manufacturer or importer, and by all manufacturers
12	and importers as a group, shall be made by the Sec-
13	retary using information provided by manufacturers
14	and importers pursuant to subsection (f), as well as
15	any other relevant information provided to or ob-
16	tained by the Secretary.
17	"(2) Measurement.—For purposes of the cal-
18	culations under this subsection and the information
19	provided under subsection (f) by the Secretary, gross
20	domestic volume shall be measured by—
21	"(A) in the case of cigarettes, the number
22	of cigarettes sold;
23	"(B) in the case of little cigars, the num-
24	ber of little cigars sold:

1	"(C) in the case of large cigars, the num-
2	ber of cigars weighing more than 3 pounds per
3	thousand sold; and
4	"(D) in the case of other classes of tobacco
5	products, in terms of number of pounds, or
6	fraction thereof, of these products sold.
7	"(f) Measurement of Gross Domestic Vol-
8	UME.—
9	"(1) In General.—Each manufacturer and
10	importer of tobacco products shall submit to the
11	Secretary a certified copy of each of the returns or
12	forms described by this paragraph that are required
13	to be filed with a Government agency on the same
14	date that those returns or forms are filed, or re-
15	quired to be filed, with such agency. The returns
16	and forms described by this paragraph are those re-
17	turns and forms related to the release of tobacco
18	products into domestic commerce, as defined by sec-
19	tion 5702(k) of the Internal Revenue Code of 1986,
20	and the repayment of the taxes imposed under chap-
21	ter 52 of such Code (ATF Form 500.24 and United
22	States Customs Form 7501 under currently applica-
23	ble regulations).
24	"(2) Penalties.—Any person that knowingly
25	fails to provide information required under this sub-

- section or that provides false information under this
 subsection shall be subject to the penalties described
 in section 1003 of title 18, United States Code. In
 addition, such person may be subject to a civil penalty in an amount not to exceed 2 percent of the
 value of the kind of tobacco products manufactured
 or imported by such person during the applicable
 quarter, as determined by the Secretary.
- 9 "(g) EFFECTIVE DATE.—The user fees prescribed by 10 this section shall be assessed in fiscal year 2007, based 11 on domestic sales of tobacco products during fiscal year 12 2006 and shall be assessed in each fiscal year thereafter.".

13 SEC. 232. INTERIM FINAL RULE.

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- (a) CIGARETTES AND SMOKELESS TOBACCO.—
- 15 (1) IN GENERAL.—Not later than 30 days after
 16 the date of enactment of this Act, the Secretary of
 17 Health and Human Services shall publish in the
 18 Federal Register an interim final rule regarding
 19 cigarettes and smokeless tobacco, which is hereby
 20 deemed to be in compliance with the Administrative
 21 Procedures Act and other applicable law.
 - (2) Contents of Rule.—Except as provided in this subsection, the interim final rule published under paragraph (1), shall be identical in its provisions to part 897 of the regulations promulgated by

1	the Secretary of Health and Human Services in the
2	August 28, 1996, issue of the Federal Register (61
3	Fed. Reg., 44615–44618). Such rule shall—
4	(A) provide for the designation of jurisdic-
5	tional authority that is in accordance with this
6	subsection;
7	(B) strike Subpart C—Labeling and sec-
8	tion $897.32(e)$; and
9	(C) become effective not later than 1 year
10	after the date of enactment of this Act.
11	(3) Amendments to rule.—Prior to making
12	amendments to the rule published under paragraph
13	(1), the Secretary shall promulgate a proposed rule
14	in accordance with the Administrative Procedures
15	Act.
16	(4) Rule of construction.—Except as pro-
17	vided in paragraph (3), nothing in this section shall
18	be construed to limit the authority of the Secretary
19	to amend, in accordance with the Administrative
20	Procedures Act, the regulation promulgated pursu-
21	ant to this section.
22	(b) Limitation on Advisory Opinions.—As of the
23	date of enactment of this Act, the following documents
24	issued by the Food and Drug Administration shall not
25	constitute advisory opinions under section 10.85(d)(1) of

- 1 title 21, Code of Federal Regulations, except as they apply
- 2 to tobacco products, and shall not be cited by the Sec-
- 3 retary of Health and Human Services or the Food and
- 4 Drug Administration as binding precedent:
- 5 (1) The preamble to the proposed rule in the
- 6 document entitled "Regulations Restricting the Sale
- 7 and Distribution of Cigarettes and Smokeless To-
- 8 bacco Products to Protect Children and Adoles-
- 9 cents" (60 Fed. Reg. 41314–41372 (August 11,
- 10 1995)).
- 11 (2) The document entitled "Nicotine in Ciga-
- 12 rettes and Smokeless Tobacco Products is a Drug
- and These Products Are Nicotine Delivery Devices
- 14 Under the Federal Food, Drug, and Cosmetic Act"
- 15 (60 Fed. Reg. 41453–41787 (August 11, 1995)).
- 16 (3) The preamble to the final rule in the docu-
- ment entitled "Regulations Restricting the Sale and
- 18 Distribution of Cigarettes and Smokeless Tobacco to
- 19 Protect Children and Adolescents" (61 Fed. Reg.
- 20 44396–44615 (August 28, 1996)).
- 21 (4) The document entitled "Nicotine in Ciga-
- rettes and Smokeless Tobacco is a Drug and These
- 23 Products are Nicotine Delivery Devices Under the
- 24 Federal Food, Drug, and Cosmetic Act; Jurisdic-

1	tional Determination" (61 Fed. Reg. 44619–45318
2	(August 28, 1996)).
3	SEC. 233. CONFORMING AND OTHER AMENDMENTS TO GEN-
4	ERAL PROVISIONS.
5	(a) Amendment of Federal Food, Drug, and
6	Cosmetic Act.—Except as otherwise expressly provided,
7	whenever in this section an amendment is expressed in
8	terms of an amendment to, or repeal of, a section or other
9	provision, the reference is to a section or other provision
10	of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11	301 et seq.).
12	(b) Section 301.—Section 301 (21 U.S.C. 331) is
13	amended—
14	(1) in subsection (a), by inserting "tobacco
15	product," after "device,";
16	(2) in subsection (b), by inserting "tobacco
17	product," after "device,";
18	(3) in subsection (c), by inserting "tobacco
19	product," after "device,";
20	(4) in subsection (e), by striking "515(f), or
21	519" and inserting "515(f), 519, or 909";
22	(5) in subsection (g), by inserting "tobacco
23	product," after "device,";
24	(6) in subsection (h), by inserting "tobacco
25	product," after "device,";

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1
              (7) in subsection (j), by striking "708, or 721"
 2
         and inserting "708, 721, 904, 905, 906, 907, 908,
 3
         909, or section 921(b)";
 4
             (8) in subsection (k), by inserting "tobacco
         product," after "device,";
 5
 6
             (9) by striking subsection (p) and inserting the
 7
         following:
         "(p) The failure to register in accordance with section
 8
    510 or 905, the failure to provide any information re-
    quired by section 510(j), 510(k), 905(i), or 905(j), or the
10
11
    failure to provide a notice required by section 510(j)(2)
    or 905(i)(2).";
12
13
              (10) by striking subsection (q)(1) and inserting
14
         the following:
         "(q)(1) The failure or refusal—
15
              "(A) to comply with any requirement prescribed
16
17
         under section 518, 520(g), 903(b)(8), or 908, or
18
         condition
                         prescribed
                                          under
                                                       section
19
         903(b)(6)(B)(ii)(II);
             "(B) to furnish any notification or other mate-
20
21
         rial or information required by or under section 519,
22
         520(g), 904, 909, or section 921; or
23
              "(C) to comply with a requirement under sec-
         tion 522 or 913.";
24
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- 1 (11) in subsection (q)(2), by striking "device,"
- and inserting "device or tobacco product,";
- 3 (12) in subsection (r), by inserting "or tobacco
- 4 product" after "device" each time that it appears;
- 5 and
- 6 (13) by adding at the end the following:
- 7 "(aa) The sale of tobacco products in violation of a
- 8 no-tobacco-sale order issued under section 303(f).
- 9 "(bb) The introduction or delivery for introduction
- 10 into interstate commerce of a tobacco product in violation
- 11 of section 911.
- 12 "(cc)(1) Forging, counterfeiting, simulating, or false-
- 13 ly representing, or without proper authority using any
- 14 mark, stamp (including tax stamp), tag, label, or other
- 15 identification device upon any tobacco product or con-
- 16 tainer or labeling thereof so as to render such tobacco
- 17 product a counterfeit tobacco product.
- 18 "(2) Making, selling, disposing of, or keeping in pos-
- 19 session, control, or custody, or concealing any punch, die,
- 20 plate, stone, or other item that is designed to print, im-
- 21 print, or reproduce the trademark, trade name, or other
- 22 identifying mark, imprint, or device of another or any like-
- 23 ness of any of the foregoing upon any tobacco product or
- 24 container or labeling thereof so as to render such tobacco
- 25 product a counterfeit tobacco product.

1	"(3) The doing of any act that causes a tobacco prod-
2	uct to be a counterfeit tobacco product, or the sale or dis-
3	pensing, or the holding for sale or dispensing, of a coun-
4	terfeit tobacco product.
5	"(dd) The charitable distribution of tobacco products.
6	"(ee) The failure of a manufacturer or distributor to
7	notify the Attorney General of their knowledge of tobacco
8	products used in illicit trade.".
9	(e) Section 303.—Section 303 (21 U.S.C. 333(f))
10	is amended in subsection (f)—
11	(1) by striking the subsection heading and in-
12	serting the following:
13	"(f) Civil Penalties; No-Tobacco-Sale Or-
14	DERS.—'';
15	(2) in paragraph (1)(A), by inserting "or to-
16	bacco products" after "devices";
17	(3) in paragraph (2)(C), by striking "paragraph
18	(3)(A)" and inserting "paragraph (4)(A)";
19	(4) by redesignating paragraphs (3), (4), and
20	(5) as paragraphs (4), (5), and (6), and inserting
21	after paragraph (2) the following:
22	"(3) If the Secretary finds that a person has
23	committed repeated violations of restrictions promul-
24	gated under section 906(d) at a particular retail out-
25	let then the Secretary may impose a no-tobacco-sale

1	order on that person prohibiting the sale of tobacco
2	products in that outlet. A no-tobacco-sale order may
3	be imposed with a civil penalty under paragraph
4	(1).";
5	(5) in paragraph (4) as so redesignated—
6	(A) in subparagraph (A)—
7	(i) by striking "assessed" the first
8	time it appears and inserting "assessed, or
9	a no-tobacco-sale order may be imposed,";
10	and
11	(ii) by striking "penalty" and insert-
12	ing "penalty, or upon whom a no-tobacco-
13	order is to be imposed,";
14	(B) in subparagraph (B)—
15	(i) by inserting after "penalty," the
16	following: "or the period to be covered by
17	a no-tobacco-sale order,"; and
18	(ii) by adding at the end the fol-
19	lowing: "A no-tobacco-sale order perma-
20	nently prohibiting an individual retail out-
21	let from selling tobacco products shall in-
22	clude provisions that allow the outlet, after
23	a specified period of time, to request that
24	the Secretary compromise, modify, or ter-
25	minate the order.": and

1	(C) by adding at the end, the following:
2	"(D) The Secretary may compromise, mod-
3	ify, or terminate, with or without conditions,
4	any no-tobacco-sale order.";
5	(6) in paragraph (5) as so redesignated—
6	(A) by striking "(3)(A)" as redesignated,
7	and inserting "(4)(A)";
8	(B) by inserting "or the imposition of a
9	no-tobacco-sale order" after "penalty" the first
10	2 places it appears; and
11	(C) by striking "issued." and inserting
12	"issued, or on which the no-tobacco-sale order
13	was imposed, as the case may be."; and
14	(7) in paragraph (6), as so redesignated, by
15	striking "paragraph (4)" each place it appears and
16	inserting "paragraph (5)".
17	(d) Section 304.—Section 304 (21 U.S.C. 334) is
18	amended—
19	(1) in subsection $(a)(2)$ —
20	(A) by striking "and" before "(D)"; and
21	(B) by striking "device." and inserting the
22	following: ", (E) Any adulterated or misbranded
23	tobacco product.";
24	(2) in subsection (d)(1), by inserting "tobacco
25	product," after "device,";

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(3) in subsection (g)(1), by inserting "or to-
 1
        bacco product" after "device" each place it appears;
 2
 3
        and
             (4) in subsection (g)(2)(A), by inserting "or to-
 4
        bacco product" after "device" each place it appears.
 5
 6
        (e) Section 702.—Section 702(a) (21
 7
    372(a)) is amended—
             (1) by inserting "(1)" after "(a)"; and
 8
 9
             (2) by adding at the end thereof the following:
10
        "(2) For a tobacco product, to the extent feasible,
    the Secretary shall contract with the States in accordance
11
12
    with paragraph (1) to carry out inspections of retailers
    within that State in connection with the enforcement of
    this Act.".
14
15
        (f) Section 703.—Section 703 (21 U.S.C. 373) is
   amended—
16
17
             (1) by inserting "tobacco product," after "de-
18
        vice," each place it appears; and
19
             (2) by inserting "tobacco products," after "de-
        vices," each place it appears.
20
21
        (g) Section 704.—Section 704 (21 U.S.C. 374) is
22
    amended—
23
             (1) in subsection (a)(1)(A), by inserting "to-
24
        bacco products," after "devices," each place it ap-
25
        pears;
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1	(2) in subsection (a)(1)(B), by inserting "or to-
2	bacco product" after "restricted devices" each place
3	it appears; and
4	(3) in subsection (b), by inserting "tobacco
5	product," after "device,".
6	(h) Section 705.—Section 705(b) (21 U.S.C.
7	375(b)) is amended by inserting "tobacco products," after
8	"devices,".
9	(i) Section 709.—Section 709 (21 U.S.C. 379) is
10	amended by inserting "or tobacco product" after "device".
11	(j) Section 801.—Section 801 (21 U.S.C. 381) is
12	amended—
13	(1) in subsection (a)—
14	(A) by inserting "tobacco products," after
15	"devices," the first time it appears;
16	(B) by inserting "or section 905(j)" after
17	"section 510"; and
18	(C) by striking "drugs or devices" each
19	time it appears and inserting "drugs, devices,
20	or tobacco products";
21	(2) in subsection (e)(1), by inserting "tobacco
22	product," after "device,"; and
23	(3) by adding at the end the following:
24	" $(p)(1)$ Not later than 2 years after the date of enact-
25	ment of the Family Smoking Prevention and Tobacco

- 1 Control Act, and annually thereafter, the Secretary shall
- 2 submit to the Committee on Health, Education, Labor,
- 3 and Pensions of the Senate and the Committee on Energy
- 4 and Commerce of the House of Representatives, a report
- 5 regarding—
- 6 "(A) the nature, extent, and destination of
- 7 United States tobacco product exports that do not
- 8 conform to tobacco product standards established
- 9 pursuant to this Act;
- 10 "(B) the public health implications of such ex-
- ports, including any evidence of a negative public
- health impact; and
- 13 "(C) recommendations or assessments of policy
- 14 alternatives available to Congress and the Executive
- 15 Branch to reduce any negative public health impact
- 16 caused by such exports.
- 17 "(2) The Secretary is authorized to establish appro-
- 18 priate information disclosure requirements to carry out
- 19 this subsection.".
- 20 (k) Section 1003.—Section 1003(d)(2)(C) (as re-
- 21 designated by section 231(a)) is amended—
- 22 (1) by striking "and" after "cosmetics,"; and
- 23 (2) inserting a comma and "and tobacco prod-
- 24 ucts" after "devices".
- 25 (l) Guidance and Effective Dates.—

1	(1) IN GENERAL.—The Secretary of Health and
2	Human Services shall issue guidance—
3	(A) defining the term "repeated violation",
4	as used in section 303(f) of the Federal Food,
5	Drug, and Cosmetic Act (21 U.S.C. 333(f)) as
6	amended by subsection (c), by identifying the
7	number of violations of particular requirements
8	over a specified period of time at a particular
9	retail outlet that constitute a repeated violation;
10	(B) providing for timely and effective no-
11	tice to the retailer of each alleged violation at
12	a particular retail outlet;
13	(C) providing for an expedited procedure
14	for the administrative appeal of an alleged vio-
15	lation;
16	(D) providing that a person may not be
17	charged with a violation at a particular retail
18	outlet unless the Secretary has provided notice
19	to the retailer of all previous violations at that
20	outlet;
21	(E) establishing a period of time during
22	which, if there are no violations by a particular
23	retail outlet, that outlet will not be considered
24	to have been the site of repeated violations
25	when the next violation occurs; and

1	(F) providing that good faith reliance on
2	the presentation of a false government issued
3	photographic identification that contains a date
4	of birth does not constitute a violation of any
5	minimum age requirement for the sale of to-
6	bacco products if the retailer has taken effective
7	steps to prevent such violations, including—
8	(i) adopting and enforcing a written
9	policy against sales to minors;
10	(ii) informing its employees of all ap-
11	plicable laws;
12	(iii) establishing disciplinary sanctions
13	for employee noncompliance; and
14	(iv) requiring its employees to verify
15	age by way of photographic identification
16	or electronic scanning device.
17	(2) General effective date.—The amend-
18	ments made by subsection (c), other than the
19	amendment made by paragraph (2) of such sub-
20	section, shall take effect upon the issuance of guid-
21	ance described in paragraph (1).
22	(3) Special effective date.—The amend-
23	ments made by paragraph (2) of subsection (c) shall
24	take effect on the date of enactment of this Act.

1	PART II—TOBACCO PRODUCT WARNINGS; CON-
2	STITUENT AND SMOKE CCONSTITUENT DIS-
3	CLOSURE
4	SEC. 235. CIGARETTE LABEL AND ADVERTISING WARNINGS.
5	Section 4 of the Federal Cigarette Labeling and Ad-
6	vertising Act (15 U.S.C. 1333) is amended to read as fol-
7	lows:
8	"SEC. 4. LABELING.
9	"(a) Label Requirements.—
10	"(1) IN GENERAL.—It shall be unlawful for any
11	person to manufacture, package, sell, offer to sell,
12	distribute, or import for sale or distribution within
13	the United States any cigarettes the package of
14	which fails to bear, in accordance with the require-
15	ments of this section, one of the following labels:
16	"'WARNING: Cigarettes are addictive
17	"'WARNING: Tobacco smoke can harm your
18	children
19	"'WARNING: Cigarettes cause fatal lung dis-
20	ease
21	"'WARNING: Cigarettes cause cancer
22	"'WARNING: Cigarettes cause strokes and
23	heart disease
24	"'WARNING: Smoking during pregnancy can
25	harm your baby
26	"'WARNING: Smoking can kill you

1	"'WARNING: Tobacco smoke causes fatal lung
2	disease in non-smokers

"'WARNING: Quitting smoking now greatly reduces serious risks to your health'.

"(2) Placement; Typography; etc.—

"(A) IN GENERAL.—Each label statement required by paragraph (1) shall be located in the upper portion of the front and rear panels of the package, directly on the package underneath the cellophane or other clear wrapping. Except as provided in subparagraph (B), each label statement shall comprise at least the top 30 percent of the front and rear panels of the package. The word 'WARNING' shall appear in capital letters and all text shall be in conspicuous and legible 17-point type, unless the text of the label statement would occupy more than 70 percent of such area, in which case the text may be in a smaller conspicuous and legible type size, provided that at least 60 percent of such area is occupied by required text. The text shall be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package, in an

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alternating fashion under the plan submitted under subsection (b)(4).

"(B) HINGED LID BOXES.—For any cigarette brand package manufactured or distributed before January 1, 2000, which employs a hinged lid style (if such packaging was used for that brand in commerce prior to June 21, 1997), the label statement required by paragraph (1) shall be located on the hinged lid area of the package, even if such area is less than 25 percent of the area of the front panel. Except as provided in this paragraph, the provisions of this subsection shall apply to such packages.

"(3) Does not apply to foreign do not apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture, package, or import cigarettes for sale or distribution within the United States.

"(4) APPLICABILITY TO RETAILERS.—A retailer of cigarettes shall not be in violation of this subsection for packaging that is supplied to the retailer by a tobacco product manufacturer, importer, or distributor and is not altered by the retailer in a way

that is material to the requirements of this subsection except that this paragraph shall not relieve a retailer of liability if the retailer sells or distributes tobacco products that are not labeled in accordance with this subsection.

"(b) Advertising Requirements.—

"(1) IN GENERAL.—It shall be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a) of this section.

"(2) Typography, etc.—Each label statement required by subsection (a) of this section in cigarette advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent (including a smoke constituent) yield shall comprise at least 20 percent of the area of the advertisement and shall appear in a conspicuous and prominent format and location at the top of each advertisement within the trim area. The Secretary may revise the required type sizes in such

area in such manner as the Secretary determines ap-1 2 propriate. The word 'WARNING' shall appear in 3 capital letters, and each label statement shall appear 4 in conspicuous and legible type. The text of the label 5 statement shall be black if the background is white 6 and white if the background is black, under the plan 7 submitted under paragraph (4) of this subsection. 8 The label statements shall be enclosed by a rectan-9 gular border that is the same color as the letters of 10 the statements and that is the width of the first downstroke of the capital 'W' of the word 'WARN-11 12 ING' in the label statements. The text of such label 13 statements shall be in a typeface pro rata to the fol-14 lowing requirements: 45-point type for a whole-page 15 broadsheet newspaper advertisement; 39-point type 16 for a half-page broadsheet newspaper advertisement; 17 39-point type for a whole-page tabloid newspaper ad-18 vertisement; 27-point type for a half-page tabloid 19 newspaper advertisement; 31.5-point type for a dou-20 ble page spread magazine or whole-page magazine 21 advertisement; 22.5-point type for a 28 centimeter 22 by 3 column advertisement; and 15-point type for a 23 20 centimeter by 2 column advertisement. The label 24 statements shall be in English, except that in the 25 case of—

- 1 "(A) an advertisement that appears in a 2 newspaper, magazine, periodical, or other publi-3 cation that is not in English, the statements 4 shall appear in the predominant language of the 5 publication; and
 - "(B) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.
 - "(3) MATCHBOOKS.—Notwithstanding paragraph (2), for matchbooks (defined as containing not more than 20 matches) customarily given away with the purchase of tobacco products, each label statement required by subsection (a) may be printed on the inside cover of the matchbook.
 - "(4) Adjustment by secretary.—The Secretary may, through a rulemaking under section 553 of title 5, United States Code, adjust the format and type sizes for the label statements required by this section or the text, format, and type sizes of any required tar, nicotine yield, or other constituent (including smoke constituent) disclosures, or to establish the text, format, and type sizes for any other disclosures required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et. seq.). The text

of any such label statements or disclosures shall be required to appear only within the 20 percent area of cigarette advertisements provided by paragraph (2) of this subsection. The Secretary shall promulgate regulations which provide for adjustments in the format and type sizes of any text required to appear in such area to ensure that the total text required to appear by law will fit within such area.

"(c) Marketing Requirements.—

"(1) RANDOM DISPLAY.—The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

"(2) ROTATION.—The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

1	"(3) Review.—The Secretary shall review each
2	plan submitted under paragraph (2) and approve it
3	if the plan—
4	"(A) will provide for the equal distribution
5	and display on packaging and the rotation re-
6	quired in advertising under this subsection; and
7	"(B) assures that all of the labels required
8	under this section will be displayed by the to-
9	bacco product manufacturer, importer, dis-
10	tributor, or retailer at the same time.
11	"(4) Applicability to retailers.—This sub-
12	section and subsection (b) apply to a retailer only if
13	that retailer is responsible for or directs the label
14	statements required under this section except that
15	this paragraph shall not relieve a retailer of liability
16	if the retailer displays, in a location open to the pub-
17	lic, an advertisement that is not labeled in accord-
18	ance with the requirements of this subsection and
19	subsection (b).".
20	SEC. 236. AUTHORITY TO REVISE CIGARETTE WARNING
21	LABEL STATEMENTS.
22	Section 4 of the Federal Cigarette Labeling and Ad-
23	vertising Act (15 U.S.C. 1333), as amended by section
24	235, is further amended by adding at the end the fol-
25	lowing:

- 1 "(d) Change in Required Statements.—The
- 2 Secretary may, by a rulemaking conducted under section
- 3 553 of title 5, United States Code, adjust the format, type
- 4 size, and text of any of the label requirements, require
- 5 color graphics to accompany the text, increase the re-
- 6 quired label area from 30 percent up to 50 percent of the
- 7 front and rear panels of the package, or establish the for-
- 8 mat, type size, and text of any other disclosures required
- 9 under the Federal Food, Drug, and Cosmetic Act (21
- 10 U.S.C. 301 et seq.), if the Secretary finds that such a
- 11 change would promote greater public understanding of the
- 12 risks associated with the use of tobacco products.".
- 13 SEC. 237. STATE REGULATION OF CIGARETTE ADVER-
- 14 TISING AND PROMOTION.
- 15 Section 5 of the Federal Cigarette Labeling and Ad-
- 16 vertising Act (15 U.S.C. 1334) is amended by adding at
- 17 the end the following:
- 18 "(c) Exception.—Notwithstanding subsection (b), a
- 19 State or locality may enact statutes and promulgate regu-
- 20 lations, based on smoking and health, that take effect
- 21 after the effective date of the Family Smoking Prevention
- 22 and Tobacco Control Act, imposing specific bans or re-
- 23 strictions on the time, place, and manner, but not content,
- 24 of the advertising or promotion of any cigarettes.".

1	SEC. 238. SMOKELESS TOBACCO LABELS AND ADVERTISING
2	WARNINGS.
3	Section 3 of the Comprehensive Smokeless Tobacco
4	Health Education Act of 1986 (15 U.S.C. 4402) is amend-
5	ed to read as follows:
6	"SEC. 3. SMOKELESS TOBACCO WARNING.
7	"(a) General Rule.—
8	"(1) It shall be unlawful for any person to man-
9	ufacture, package, sell, offer to sell, distribute, or
10	import for sale or distribution within the United
11	States any smokeless tobacco product unless the
12	product package bears, in accordance with the re-
13	quirements of this Act, one of the following labels:
14	"'WARNING: This product can cause mouth
15	cancer
16	"'WARNING: This product can cause gum dis-
17	ease and tooth loss
18	"'WARNING: This product is not a safe alter-
19	native to cigarettes
20	"'WARNING: Smokeless tobacco is addictive'.
21	"(2) Each label statement required by para-
22	graph (1) shall be—
23	"(A) located on the 2 principal display
24	panels of the package, and each label statement
25	shall comprise at least 30 percent of each such
26	display panel; and

"(B) in 17-point conspicuous and legible 1 2 type and in black text on a white background, 3 or white text on a black background, in a man-4 ner that contrasts by typography, layout, or 5 color, with all other printed material on the 6 package, in an alternating fashion under the 7 plan submitted under subsection (b)(3), except 8 that if the text of a label statement would oc-9 cupy more than 70 percent of the area specified 10 by subparagraph (A), such text may appear in a smaller type size, so long as at least 60 per-12 cent of such warning area is occupied by the 13 label statement.

> "(3) The label statements required by paragraph (1) shall be introduced by each tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products concurrently into the distribution chain of such products.

> "(4) The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of any smokeless tobacco product that does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

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1 "(5) A retailer of smokeless tobacco products 2 shall not be in violation of this subsection for pack-3 aging that is supplied to the retailer by a tobacco 4 products manufacturer, importer, or distributor and 5 that is not altered by the retailer unless the retailer 6 offers for sale, sells, or distributes a smokeless to-7 bacco product that is not labeled in accordance with 8 this subsection.

"(b) REQUIRED LABELS.—

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- "(1) It shall be unlawful for any tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products to advertise or cause to be advertised within the United States any smokeless tobacco product unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).
- "(2) Each label statement required by subsection (a) in smokeless tobacco advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent yield shall—
- 24 "(A) comprise at least 20 percent of the 25 area of the advertisement, and the warning area

shall be delineated by a dividing line of contrasting color from the advertisement; and

"(B) the word 'WARNING' shall appear in capital letters and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black on a white background, or white on a black background, in an alternating fashion under the plan submitted under paragraph (3).

"(3)(A) The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

"(B) The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of smokeless tobacco product in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

1	"(C) The Secretary shall review each plan sub-
2	mitted under subparagraph (B) and approve it if the
3	plan—
4	"(i) will provide for the equal distribution
5	and display on packaging and the rotation re-
6	quired in advertising under this subsection; and
7	"(ii) assures that all of the labels required
8	under this section will be displayed by the to-
9	bacco product manufacturer, importer, dis-
10	tributor, or retailer at the same time.
11	"(D) This paragraph applies to a retailer only
12	if that retailer is responsible for or directs the label
13	statements under this section, unless the retailer dis-
14	plays in a location open to the public, an advertise-
15	ment that is not labeled in accordance with the re-
16	quirements of this subsection.
17	"(c) Television and Radio Advertising.—It is
18	unlawful to advertise smokeless tobacco on any medium
19	of electronic communications subject to the jurisdiction of
20	the Federal Communications Commission.".
21	SEC. 239. AUTHORITY TO REVISE SMOKELESS TOBACCO
22	PRODUCT WARNING LABEL STATEMENTS.
23	Section 3 of the Comprehensive Smokeless Tobacco
24	Health Education Act of 1986 (15 U.S.C. 4402), as

- 1 amended by section 237, is further amended by adding
- 2 at the end the following:
- 3 "(d) Authority to Revise WARNING Label
- 4 STATEMENTS.—The Secretary may, by a rulemaking con-
- 5 ducted under section 553 of title 5, United States Code,
- 6 adjust the format, type size, and text of any of the label
- 7 requirements, require color graphics to accompany the
- 8 text, increase the required label area from 30 percent up
- 9 to 50 percent of the front and rear panels of the package,
- 10 or establish the format, type size, and text of any other
- 11 disclosures required under the Federal Food, Drug, and
- 12 Cosmetic Act (21 U.S.C. 301 et seq.), if the Secretary
- 13 finds that such a change would promote greater public un-
- 14 derstanding of the risks associated with the use of smoke-
- 15 less tobacco products.".
- 16 SEC. 240. TAR, NICOTINE, AND OTHER SMOKE CON-
- 17 STITUENT DISCLOSURE TO THE PUBLIC.
- 18 Section 4(a) of the Federal Cigarette Labeling and
- 19 Advertising Act (15 U.S.C. 1333 (a)), as amended by sec-
- 20 tion 235, is further amended by adding at the end the
- 21 following:
- 22 "(4)(A) The Secretary shall, by a rulemaking
- conducted under section 553 of title 5, United
- 24 States Code, determine (in the Secretary's sole dis-
- cretion) whether cigarette and other tobacco product

manufacturers shall be required to include in the area of each cigarette advertisement specified by subsection (b) of this section, or on the package label, or both, the tar and nicotine yields of the advertised or packaged brand. Any such disclosure shall be in accordance with the methodology established under such regulations, shall conform to the type size requirements of subsection (b) of this section, and shall appear within the area specified in subsection (b) of this section.

"(B) Any differences between the requirements established by the Secretary under subparagraph (A) and tar and nicotine yield reporting requirements established by the Federal Trade Commission shall be resolved by a memorandum of understanding between the Secretary and the Federal Trade Commission.

"(C) In addition to the disclosures required by subparagraph (A) of this paragraph, the Secretary may, under a rulemaking conducted under section 553 of title 5, United States Code, prescribe disclosure requirements regarding the level of any cigarette or other tobacco product constituent including any smoke constituent. Any such disclosure may be required if the Secretary determines that disclosure

1 would be of benefit to the public health, or otherwise 2 would increase consumer awareness of the health 3 consequences of the use of tobacco products, except that no such prescribed disclosure shall be required on the face of any cigarette package or advertise-5 6 ment. Nothing in this section shall prohibit the Sec-7 retary from requiring such prescribed disclosure 8 through a cigarette or other tobacco product pack-9 age or advertisement insert, or by any other means 10 under the Federal Food, Drug, and Cosmetic Act 11 (21 U.S.C. 301 et seq.).

"(D) This paragraph applies to a retailer only if that retailer is responsible for or directs the label statements required under this section, except that this paragraph shall not relieve a retailer of liability if the retailer sells or distributes tobacco products that are not labeled in accordance with the requirements of this subsection.".

PART III—PREVENTION OF ILLICIT TRADE IN

20 TOBACCO PRODUCTS

- 21 SEC. 241. LABELING, RECORDKEEPING, RECORDS INSPEC-
- 22 **TION.**

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- Chapter IX of the Federal Food, Drug, and Cosmetic
- 24 Act, as added by section 231, is further amended by add-
- 25 ing at the end the following:

1	"SEC. 921. LABELING, RECORDKEEPING, RECORDS INSPEC-
2	TION.
3	"(a) Origin Labeling.—The label, packaging, and
4	shipping containers of tobacco products for introduction
5	or delivery for introduction into interstate commerce in the
6	United States shall bear the statement 'sale only allowed
7	in the United States.'
8	"(b) REGULATIONS CONCERNING RECORDKEEPING
9	FOR TRACKING AND TRACING.—
10	"(1) In general.—Not later than 9 months
11	after the date of enactment of the Family Smoking
12	Prevention and Tobacco Control Act, the Secretary
13	shall promulgate regulations regarding the establish-
14	ment and maintenance of records by any person who
15	manufactures, processes, transports, distributes, re-
16	ceives, packages, holds, exports, or imports tobacco
17	products.
18	"(2) Inspection.—In promulgating the regula-
19	tions described in paragraph (1), the Secretary shall
20	consider which records are needed for inspection to
21	monitor the movement of tobacco products from the
22	point of manufacture through distribution to retail
23	outlets to assist in investigating potential illicit
24	trade, smuggling or counterfeiting of tobacco prod-
25	ucts.

- 1 "(3) Codes.—The Secretary may require codes 2 on the labels of tobacco products or other designs or 3 devices for the purpose of tracking or tracing the to-4 bacco product through the distribution system.
- 5 "(4) Size of business.—The Secretary shall 6 take into account the size of a business in promul-7 gating regulations under this section.
- 8 "(5) RECORDKEEPING BY RETAILERS.—The
 9 Secretary shall not require any retailer to maintain
 10 records relating to individual purchasers of tobacco
 11 products for personal consumption
- 11 products for personal consumption. 12 "(c) Records Inspection.—If the Secretary has a reasonable belief that a tobacco product is part of an illicit trade or smuggling or is a counterfeit product, each person 14 15 who manufactures, processes, transports, distributes, receives, holds, packages, exports, or imports tobacco prod-16 ucts shall, at the request of an officer or employee duly 17 18 designated by the Secretary, permit such officer or employee, at reasonable times and within reasonable limits 19 20 and in a reasonable manner, upon the presentation of ap-21 propriate credentials and a written notice to such person, to have access to and copy all records (including financial 23 records) relating to such article that are needed to assist the Secretary in investigating potential illicit trade, smuggling or counterfeiting of tobacco products.

1	"(d) Knowledge of Illegal Transaction.—
2	"(1) IN GENERAL.—If the manufacturer or dis-
3	tributor of a tobacco product has knowledge which
4	reasonably supports the conclusion that a tobacco
5	product manufactured or distributed by such manu-
6	facturer or distributor that has left the control of
7	such person may be or has been—
8	"(A) imported, exported, distributed or of-
9	fered for sale in interstate commerce by a per-
10	son without paying duties or taxes required by
11	law; or
12	"(B) imported, exported, distributed or di-
13	verted for possible illicit marketing, the manu-
14	facturer or distributor shall promptly notify the
15	Attorney General of such knowledge.
16	"(2) Knowledge defined.—For purposes of
17	this subsection, the term 'knowledge' as applied to
18	a manufacturer or distributor means—
19	"(A) the actual knowledge that the manu-
20	facturer or distributor had; or
21	"(B) the knowledge which a reasonable
22	person would have had under like circumstances
23	or which would have been obtained upon the ex-
24	ercise of due care.".

1 SEC. 242. STUDY AND REPORT.

2 (a) STUDY.—The Comptroller General of the Un

- 3 States shall conduct a study of cross-border trade in to-
- 4 bacco products to—
- 5 (1) collect data on cross-border trade in tobacco
- 6 products, including illicit trade and trade of counter-
- 7 feit tobacco products and make recommendations on
- 8 the monitoring of such trade;
- 9 (2) collect data on cross-border advertising (any
- advertising intended to be broadcast, transmitted, or
- distributed from the United States to another coun-
- try) of tobacco products and make recommendations
- on how to prevent or eliminate, and what tech-
- 14 nologies could help facilitate the elimination of,
- 15 cross-border advertising.
- 16 (b) Report.—Not later than 18 months after the
- 17 date of enactment of this Act, the Comptroller General
- 18 of the United States shall submit to the Committee on
- 19 Health, Education, Labor, and Pensions of the Senate and
- 20 the Committee on Energy and Commerce of the House
- 21 of Representatives a report on the study described in sub-
- 22 section (a).

1	TITLE III—RESPONSIBLE MAR-
2	KETING AND CONSUMER
3	AWARENESS
4	Subtitle A—General Provisions
5	SEC. 301. NUTRITION LABELING OF RESTAURANT FOODS.
6	Section 403(q)(5) of the Federal Food, Drug, and
7	Cosmetic Act (21 U.S.C. 343(q)(5)(A)(i)) is amended—
8	(1) in clause (A)—
9	(A) in subclause (i), by inserting "except
10	as provided in clauses (H) and (I)," before
11	"which" the first place it appears; and
12	(B) in subclause (ii), by inserting "except
13	as provided in clauses (H) and (I)," before
14	"which" the first place it appears; and
15	(2) by adding at the end the following:
16	"(H) Restaurants and retail food estab-
17	LISHMENTS.—
18	"(i) In general.—Except for food de-
19	scribed in subclause (iii), in the case of food
20	that is served, processed, or prepared in a res-
21	taurant or similar retail food establishment that
22	is part of a chain with 20 or more locations
23	doing business under the same trade name (re-
24	gardless of the type of ownership of the loca-
25	tions), the restaurant or establishment shall

1	disclose the information described in subclause
2	(ii).
3	"(ii) Information required to be dis-
4	CLOSED.—Except as provided in subclause (iii),
5	the establishment shall disclose—
6	"(I)(aa) in a statement adjacent to
7	the name of the food on any menu listing
8	the food for sale, or by any other means
9	deemed equivalent by the Secretary, the
10	number of calories, grams of saturated fat
11	plus trans fat, and milligrams of sodium
12	contained in a standard serving of the
13	food, as usually offered for sale, in a clear
14	and conspicuous manner; and
15	"(bb) information, specified by the
16	Secretary by regulation, designed to enable
17	the public to understand, in the context of
18	a total daily diet, the significance of the
19	nutrition information that is provided; and
20	"(II) in a statement adjacent to the
21	name of the food on any menu board or
22	other sign listing the food for sale, or by
23	any other means deemed equivalent by the
24	Secretary—

1	"(aa) the number of calories con-
2	tained in a serving of the food, as
3	usually offered for sale, in a clear and
4	conspicuous manner; and
5	"(bb) notification that the infor-
6	mation required by subitems (aa) and
7	(bb) of item (I) shall be provided in
8	writing at the request of a prospective
9	purchaser.
10	"(iii) Nonapplicability to certain
11	FOOD.—This clause does not apply to—
12	"(I) items that are not listed on a
13	menu or menu board (such as condiments
14	and other items placed on the table or
15	counter for general use); or
16	"(II) daily specials, temporary menu
17	items, or other irregular menu items, as
18	specified by the Secretary by regulation.
19	"(iv) Self-service facilities.—In the
20	case of food sold at a salad bar, buffet line, caf-
21	eteria line, or similar self-service facility, a res-
22	taurant or other establishment shall place a
23	sign that lists calories per standard serving ad-
24	jacent to each food offered.

1	"(v) Voluntary provision of nutri-
2	TION INFORMATION; STATE REGULATION OF
3	NUTRITION INFORMATION FOR RESTAURANT
4	FOOD.—
5	"(I) Retail food establish-
6	MENTS.—Nothing in this clause precludes
7	a restaurant or similar retail food estab-
8	lishment from providing additional nutri-
9	tion information, voluntarily, if the infor-
10	mation complies with the nutrition labeling
11	requirements contained in this subpara-
12	graph.
13	"(II) STATE OR LOCAL REQUIRE-
14	MENTS.—Nothing in this clause precludes
15	a State or political subdivision of a State
16	from requiring that a restaurant or similar
17	food establishment provide nutrition infor-
18	mation in addition to that required under
19	this clause.
20	"(vi) Regulations.—
21	"(I) Proposed regulation.—Not
22	later than 1 year after the date of enact-
23	ment of this clause, the Secretary shall
24	promulgate proposed regulations to carry
25	out this clause.

1	"(II) Contents.—The regulations
2	shall allow for the variations in serving
3	sizes and in food preparation that can rea-
4	sonably be expected to result from inad-
5	vertent human error, training of food serv-
6	ice workers, and other factors.
7	"(III) Final regulations.—Not
8	later than 2 years after the date of enact-
9	ment of this clause, the Secretary shall
10	promulgate final regulations to implement
11	this clause.
12	"(IV) Failure to promulgate
13	FINAL REGULATIONS BY REQUIRED
14	DATE.—If the Secretary does not promul-
15	gate final regulations under item (III) by
16	the date that is 2 years after the date of
17	enactment of this clause—
18	"(aa) the proposed regulations
19	issued in accordance with item (I)
20	shall become effective as the final reg-
21	ulations on the day after that date;
22	and
23	"(bb) the Secretary shall publish
24	in the Federal Register notice of the
25	final regulations.

1	"(I) Vending machines.—
2	"(i) In general.—In the case of an arti-
3	cle of food sold from a vending machine that—
4	"(I) does not permit a prospective
5	purchaser to examine the article so as to
6	be able to read a statement affixed to the
7	article before purchasing the article; and
8	"(II) is operated by a person that is
9	engaged in the business of owning and op-
10	erating 20 or more vending machines;
11	the vending machine operator shall provide a con-
12	spicuous sign in close proximity to the article that
13	includes a statement disclosing the number of cal-
14	ories contained in the article.
15	"(ii) Voluntary provision of nutri-
16	TION INFORMATION; STATE REGULATION OF
17	NUTRITION INFORMATION FOR VENDING MA-
18	CHINES.—
19	"(I) Vending machine opera-
20	TORS.—Nothing in this clause precludes a
21	vending machine operator from providing
22	additional nutrition information, volun-
23	tarily, if the information complies with the
24	nutrition labeling requirements contained
25	in this subparagraph.

1	"(II) STATE OR LOCAL REQUIRE-
2	MENTS.—Nothing in this title precludes a
3	State or political subdivision of a State
4	from requiring that a vending machine op-
5	erator provide nutrition information in ad-
6	dition to that required under this clause.
7	"(iii) Regulations.—
8	"(I) Proposed regulations.—Not
9	later than 1 year after the date of enact-
10	ment of this clause, the Secretary shall
11	promulgate proposed regulations to carry
12	out this clause.
13	"(II) Final regulations.—Not
14	later than 2 years after the date of enact-
15	ment of this clause, the Secretary shall
16	promulgate final regulations to implement
17	this clause.
18	"(III) FAILURE TO PROMULGATE
19	FINAL REGULATIONS BY REQUIRED
20	DATE.—If the Secretary does not promul-
21	gate final regulations under item (II) by
22	the date that is 2 years after the date of
23	enactment of this clause—
24	"(aa) the proposed regulations
25	issued in accordance with item (I)

1	shall become effective as the final reg-
2	ulations on the day after that date;
3	and
4	"(bb) the Secretary shall publish
5	in the Federal Register notice of the
6	final regulations.".
7	SEC. 302. RULEMAKING AUTHORITY FOR ADVERTISING TO
8	CHILDREN.
9	(a) Purpose.—The purpose of this section is to re-
10	store the authority of the Federal Trade Commission to
11	issue regulations that restrict the marketing or advertising
12	of foods and beverages to children under the age of 18
13	years if the Federal Trade Commission determines that
14	there is evidence that consumption of certain foods and
15	beverages is detrimental to the health of children.
16	(b) Authority.—Section 18 of the Federal Trade
17	Commission Act (15 U.S.C. 57a) is amended by striking
18	subsection (h).
19	SEC. 303. FOOD ADVERTISING IN SCHOOLS.
20	Section 10 of the Child Nutrition Act of 1966 (42
21	U.S.C. 1779), as amended by section 102 of this Act, is
22	further amended by adding at the end the following:
23	"(c) FOOD ADVERTISING.—The Secretary may pro-
24	hibit the advertising of food in participating schools if the
25	Secretary determines that consumption of the advertised

1	food has a detrimental effect on the diets or health of chil-
2	dren.".
3	CEC 204 DIGALLOWANCE OF DEDUCTIONS FOR ADVER

- 3 SEC. 304. DISALLOWANCE OF DEDUCTIONS FOR ADVER-
- 4 TISING AND MARKETING EXPENSES RELAT-
- 5 ING TO TOBACCO PRODUCT USE.
- 6 (a) In General.—Part IX of subchapter B of chap-
- 7 ter 1 of subtitle A of the Internal Revenue Code of 1986
- 8 (relating to items not deductible) is amended by adding
- 9 at the end the following new section:
- 10 "SEC. 280I. DISALLOWANCE OF DEDUCTION FOR TOBACCO
- 11 ADVERTISING AND MARKETING EXPENSES.
- "No deduction shall be allowed under this chapter for
- 13 expenses relating to advertising or marketing cigars, ciga-
- 14 rettes, smokeless tobacco, pipe tobacco, or any similar to-
- 15 bacco product. For purposes of this section, any term used
- 16 in this section which is also used in section 5702 shall
- 17 have the same meaning given such term by section 5702.".
- 18 (b) Conforming Amendment.—The table of sec-
- 19 tions for such part IX is amended by adding after the
- 20 item relating to section 280H the following new item:
 - "Sec. 280I. Disallowance of deduction for tobacco advertising and marketing expenses.".
- 21 (c) Effective Date.—The amendments made by
- 22 this section shall apply to taxable years beginning after
- 23 the date of the enactment of this Act.

1	SEC. 305. FEDERAL-STATE TOBACCO COUNTER-ADVER-
2	TISING PROGRAMS.
3	Part P of title III of the Public Health Service Act
4	(42 U.S.C. 280g et seq.), as amended in section 211, is
5	further amended by adding at the end the following:
6	"SEC. 399Q. FEDERAL-STATE TOBACCO COUNTER-ADVER-
7	TISING PROGRAMS.
8	"(a) In General.—The Secretary, acting through
9	the Director of the Centers for Disease Control and Pre-
10	vention, shall award grants to and enter into contracts
11	with eligible entities for the implementation of national
12	and local media (such as counter-advertising) and non-
13	media campaigns designed to reduce the use of tobacco
14	products.
15	"(b) Eligibility.—To be eligible to receive a grant
16	under subsection (a), an entity shall be—
17	"(1) a public entity, including a State public
18	health department; or
19	"(2) a private, nonprofit entity that—
20	"(A) is not affiliated with a manufacturer
21	or importer of a tobacco product;
22	"(B) has demonstrated a record of con-
23	ducting a national antitobacco public education
24	campaign to effectively reduce the use of to-
25	bacco products

1	"(C) has expertise in conducting a multi-
2	media communications campaign; and
3	"(D) has expertise in developing strategies
4	that affect behavior changes in children and
5	other targeted populations.
6	"(c) Application.—An eligible entity shall submit
7	an application to the Secretary for a grant under this sec-
8	tion at such time, in such manner, and accompanied by
9	such information as the Secretary may require.
10	"(d) Use of Funds.—An eligible entity shall use
11	amounts received under a grant under this section to—
12	"(1) design and implement multimedia public
13	education and social marketing campaigns that—
14	"(A) discourage the use of tobacco prod-
15	ucts;
16	"(B) encourage the use of products de-
17	signed to enable tobacco use cessation; and
18	"(C) educate the public about the hazards
19	of environmental tobacco smoke exposure; or
20	"(2) conduct research related to the effective-
21	ness of the campaigns described in paragraph (1).
22	"(e) Allocation of Grants.—Of the amounts
23	awarded under this section, the Secretary shall award—
24	"(1) 50 percent of such amounts to eligible
25	public entities: and

1	"(2) 50 percent of such amounts to eligible pri-
2	vate, nonprofit entities.
3	"(f) Authorization of Appropriations.—There
4	are authorized to be appropriated \$200,000,000 to carry
5	out this section.".
6	Subtitle B—Penalties for Failure to
7	Reduce Teen Smoking
8	SEC. 311. CHILD CIGARETTE USE SURVEYS.
9	(a) Annual Performance Survey.—
10	(1) In general.—Not later than August 31,
11	2007, and annually thereafter, the Secretary of
12	Health and Human Services (referred to in this sec-
13	tion as the "Secretary") shall publish the results of
14	an annual cigarette survey, to be carried out after
15	the date of enactment of this Act and completed
16	prior to August 21, 2007, and prior to August 21
17	of each year thereafter, to determine—
18	(A) the percentage of all young individuals
19	who used a type of cigarette within the 30-day
20	period prior to the conduct of the survey in-
21	volved; and
22	(B) the percentage of young individuals
23	who identify each brand of each type of ciga-
24	rette as the usual brand smoked within such
25	30-day period.

1 (2) Young individuals.—For the purposes of 2 this subtitle, the term "young individuals" means in-3 dividuals who are under 18 years of age.

(b) Size and Methodology.—

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- (1) In General.—The survey referred to in subsection (a) shall be comparable in size and methodology to the Monitoring the Future survey that was completed in 1999 to measure the use of cigarettes (by brand) by youths under 18 years of age within the 30-day period prior to the conduct of the study.
- (2) Conclusive accurateness.—A survey using the methodology described in paragraph (1) shall be deemed conclusively proper, correct, and accurate for purposes of this section.
- (3) DEFINITION.—In this subtitle, the term "Monitoring the Future survey" means the combined survey of 8th, 10th, and 12th grade students that was conducted at the Institute for Social Research at the University of Michigan.
- 21 (c) REDUCTION.—The Secretary, based on a com-22 parison of the results of the first annual cigarette survey 23 referred to in subsection (a) and the Monitoring the Fu-24 ture survey referred to in subsection (b)(1), shall deter-

- 1 mine the percentage reduction (if any) in youth cigarette
- 2 use for each manufacturer of cigarettes.
- 3 (d) Participation in Survey.—Notwithstanding
- 4 any other provision of law, the Secretary may conduct a
- 5 survey under this section involving minors if the results
- 6 of such survey with respect to such minors are kept con-
- 7 fidential and not disclosed.
- 8 (e) Nonapplicability.—Chapter 35 of title 44,
- 9 United States Code, shall not apply to information re-
- 10 quired for the purposes of carrying out this section.
- 11 (f) Definition.—In this subtitle the term "ciga-
- 12 rette" has the meaning given such term in section 3(1)
- 13 of the Federal Cigarette Labeling and Advertising Act (15
- 14 U.S.C. 1332(1)).
- 15 SEC. 312. CIGARETTE USE REDUCTION GOAL AND NON-
- 16 **COMPLIANCE.**
- 17 (a) GOAL.—It shall be the cigarette use reduction
- 18 goal that each manufacturer reduce youth cigarette use
- 19 by at least 15 percent during the period between the Moni-
- 20 toring the Future survey referred to in section 311(b)(1)
- 21 and the completion of the first annual cigarette survey
- 22 (and such subsequent surveys as compared to the previous
- 23 year's survey) referred to in section 311(a).
- 24 (b) Noncompliance.—

1	(1) Industry-wide penalty.—If the Sec-
2	retary determines that the cigarette use reduction
3	goal under subsection (a) has not been achieved, the
4	Secretary shall, not later than September 10, 2007,
5	and September 10 of each year thereafter, impose
6	an industry-wide penalty on the manufacturers of
7	cigarettes in an amount that is in the aggregate
8	equal to—
9	(A) if youth cigarette use has been reduced
10	by 5 percent or less, \$6,000,000,000;
11	(B) if youth cigarette use has been reduced
12	by at least 6 percent but less than 10 percent,
13	\$4,000,000,000; and
14	(C) if youth cigarette use has been reduced
15	by at least 11 percent but less than 15 percent,
16	\$2,000,000,000.
17	(2) Payment.—The industry-wide penalty im-
18	posed under this subsection shall be paid by each
19	manufacturer based on the percentage of cigarettes
20	of each such manufacturer that are used by youth
21	(as determined under the Monitoring the Future
22	survey and compared to the cigarettes manufactured

by all manufacturers) as such percentage relates to

the total amount to be paid by all manufacturers.

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- 1 (3) Final determina—The determina2 tion of the Secretary as to the amount and allocation
 3 of a surcharge under this subtitle shall be final and
 4 the manufacturer shall pay such surcharge within 10
 5 days of the date on which the manufacturer is as6 sessed. Such payment shall be retained by the Sec7 retary pending final judicial review of what, if any,
 8 change in the surcharge is appropriate.
 - (4) Compliance by Certain Manufacturer Ers.—A manufacturer that individually complies with the goal under subsection (a) shall not be liable for the payment of any portion of the penalty under this subsection.
 - (5) LIMITATION.—With respect to cigarettes, a manufacturer with a market share of 1 percent or less of youth cigarette use shall not be liable for the payment of a surcharge under this section.
- 18 (c) Penalties Nondeductible.—The payment of 19 penalties under this subtitle shall not be considered to be 20 an ordinary and necessary expense in carrying on a trade 21 or business for purposes of the Internal Revenue Code of 22 1986 and shall not be deductible.
- 23 (d) Judicial Review.—
- 24 (1) After payment.—A manufacturer of ciga-25 rettes may seek judicial review of any action under

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- this subtitle only after the assessment involved has been paid by the manufacturer to the Department of the Treasury and only in the United States District Court for the District of Columbia.
 - (2) REVIEW BY ATTORNEY GENERAL.—Prior to the filing of an action by a manufacturer seeking judicial review of an action under this subtitle, the manufacturer shall notify the Attorney General of such intent to file and the Attorney General shall have 30 days in which to respond to the action.
 - paid under this subtitle shall be subject to judicial review by the United States Court of Appeals for the District of Columbia Circuit, based on the arbitrary and capricious standard of section 706 of title 5, United States Code. Notwithstanding any other provision of law, no court shall have the authority to stay any surcharge payment due to the Secretary under this subtitle pending judicial review until the Secretary has made or failed to make a compliance determination, as described under this subtitle, that has adversely affected the person seeking the review.
- 23 SEC. 313. ENFORCEMENT.
- 24 (a) Initial Penalty.—There is hereby imposed an 25 initial penalty on the failure of any manufacturer to make

- 1 any payment required under this subtitle within 10 days
- 2 after the date on which such payment is due.
- 3 (b) Amount of Penalty.—The amount of the pen-
- 4 alty imposed by subsection (a) on any failure with respect
- 5 to a manufacturer shall be an amount equal to 2 percent
- 6 of the penalty owed under section 312 for each day during
- 7 the noncompliance period.
- 8 (c) Noncompliance Period.—For purposes of this
- 9 section, the term "noncompliance period" means, with re-
- 10 spect to any failure to make the surcharge payment re-
- 11 quired under this subtitle, the period—
- 12 (1) beginning on the due date for such pay-
- ment; and
- 14 (2) ending on the date on which such payment
- is paid in fall.
- 16 (d) Limitations.—No penalty shall be imposed by
- 17 subsection (a) on—
- 18 (1) any failure to make a surcharge payment
- under this subtitle during any period for which it is
- established to the satisfaction of the Secretary that
- 21 none of the persons responsible for such failure
- knew or, exercising reasonable diligence, would have
- known, that such failure existed; or

1	(2) any manufacturer that produces less than 1
2	percent of cigarettes used by youth in that year (as
3	determined by the annual survey).
4	TITLE IV—REIMBURSEMENT
5	AND COVERAGE OF PREVEN-
6	TIVE SERVICES
7	SEC. 401. COVERAGE OF SUBSTANCE USE (OTHER THAN TO-
8	BACCO), DIET, EXERCISE, INJURY PREVEN-
9	TION, AND DENTAL HEALTH COUNSELING.
10	(a) Coverage.—
11	(1) In General.—Section 1861(s)(2) of the
12	Social Security Act (42 U.S.C. 1395x(s)(2)), as
13	amended by section 5112(a) of the Deficit Reduction
14	Act of 2005, is amended—
15	(A) in subparagraph (Z), by striking
16	"and" after the semicolon at the end;
17	(B) in subparagraph (AA), by adding
18	"and" after the semicolon at the end; and
19	(C) by adding at the end the following new
20	subparagraph:
21	"(BB) substance use (other than tobacco), diet,
22	exercise, injury prevention, and dental health coun-
23	seling (as defined in subsection $(ccc)(1)$);".
24	(2) Conforming amendments.—(A) Section
25	1862(a)(12) of the Social Security Act (42 U.S.C.

- 1 1395y(a)(12)) is amended by inserting "(except as 2 otherwise allowed under subsection
- 3 1861(s)(2)(BB))" after "directly supporting teeth".
- 4 (B) Clauses (i) and (ii) of section
- 5 1861(s)(2)(K) of the Social Security Act (42 U.S.C.
- 6 1395x(s)(2)(K)) are each amended by striking "sub-
- 7 section (ww)(1)" and inserting "subsections (ww)(1)
- 8 and (ccc)".
- 9 (b) Services Described.—Section 1861 of the So-
- 10 cial Security Act (42 U.S.C. 1395x), as amended by sec-
- 11 tion 5112(a) of the Deficit Reduction Act of 2005, is
- 12 amended by adding at the end the following new sub-
- 13 section:
- 14 "Substance Use (other Than Tobacco), Diet, Exercise,
- 15 Injury Prevention, and Dental Health Counseling
- 16 "(ccc) The term 'substance use (other than tobacco),
- 17 diet, exercise, injury prevention, and dental health coun-
- 18 seling' means therapy and counseling relating to substance
- 19 use (other than tobacco), diet, exercise, injury prevention,
- 20 and dental health counseling that is furnished—
- 21 "(1) by or under the supervision of a physician;
- 22 or
- 23 "(2) by any other health care professional
- 24 who—

1	"(A) is legally authorized to furnish such
2	services under State law (or the State regu-
3	latory mechanism provided by State law) of the
4	State in which the services are furnished; and
5	"(B) is authorized to receive payment for
6	other services under this title or is designated
7	by the Secretary for this purpose.".
8	(c) Payment and Elimination of Cost-Shar-
9	ING.—
10	(1) Payment and elimination of coinsur-
11	ANCE.—Section 1833(a)(1) of the Social Security
12	Act (42 U.S.C. 1395l(a)(1)) is amended—
13	(A) in subparagraph (N), by inserting "or
14	substance use (other than tobacco), diet, exer-
15	cise, injury prevention, and dental health coun-
16	seling (as defined in section 1861(ccc))" after
17	"(as defined in section 1848(j)(3))";
18	(B) by striking "and" before "(V)"; and
19	(C) by inserting before the semicolon at
20	the end the following: "and (W) with respect to
21	substance use (other than tobacco), diet, exer-
22	cise, injury prevention, and dental health coun-
23	seling (as defined in section 1861(ccc) the
24	amount paid shall be the lesser of the actual
25	charge for the services or the amount deter-

1	mined under the payment basis determined
2	under section 1848".
3	(2) Payment under physician fee sched-
4	ULE.—Section 1848(j)(3) of the Social Security Act
5	(42 U.S.C. $1395w-4(j)(3)$), as amended by section
6	5112(c) of the Deficit Reduction Act of 2005, is
7	amended by inserting "(2)(BB)," after "(2)(AA),".
8	(3) Elimination of Coinsurance in Out-
9	PATIENT HOSPITAL SETTINGS.—
10	(A) Exclusion from opd fee sched-
11	ULE.—Section 1833(t)(1)(B)(iv) of the Social
12	Security Act (42 U.S.C. 1395l(t)(1)(B)(iv)) is
13	amended by striking "and diagnostic mammog-
14	raphy" and inserting ", diagnostic mammog-
15	raphy, or substance use (other than tobacco),
16	diet, exercise, injury prevention, and dental
17	health counseling (as defined in section
18	1861(bbb))".
19	(B) Conforming amendments.—Section
20	1833(a)(2) of the Social Security Act (42
21	U.S.C. 1395l(a)(2)) is amended—
22	(i) in subparagraph (F), by striking
23	"and" after the semicolon at the end;

1	(ii) in subparagraph (G)(ii), by strik-
2	ing the comma at the end and inserting ";
3	and"; and
4	(iii) by inserting after subparagraph
5	(G)(ii) the following new subparagraph:
6	"(H) with respect to substance use (other
7	than tobacco), diet, exercise, injury prevention,
8	and dental health counseling (as defined in sec-
9	tion 1861(ccc)) furnished by an outpatient de-
10	partment of a hospital, the amount determined
11	under paragraph (1)(W),".
12	(4) Elimination of Deductible.—The first
13	sentence of section 1833(b) of the Social Security
14	Act (42 U.S.C. 1395l(b)), as amended by section
15	5112(e) of the Deficit Reduction Act of 2005, is
16	amended—
17	(A) by striking "and" before "(7)"; and
18	(B) by inserting before the period at the
19	end the following: ", and (8) such deductible
20	shall not apply with respect to substance use
21	(other than tobacco), diet, exercise, injury pre-
22	vention, and dental health counseling (as de-
23	fined in section 1861(ccc))".
24	(d) Application of Limits on Billing.—Section
25	1842(b)(18)(C) of the Social Security Act (42 U.S.C.

1	1395u(b)(18)(C)) is amended by adding at the end the
2	following new clause:
3	"(vii) Any health care professional designated
4	under section 1861(ccc)(2)(B) to perform substance
5	use (other than tobacco), diet, exercise, injury pre-
6	vention, and dental health counseling that is not oth-
7	erwise described in this subparagraph.".
8	(e) Effective Date.—The amendments made by
9	this section shall apply to services furnished on and after
10	January 1, 2007.
11	SEC. 402. ENCOURAGEMENT OF CESSATION OF TOBACCO
12	USE.
13	(a) Medicare Coverage of Counseling and
14	PHARMACOTHERAPY FOR CESSATION OF TOBACCO
15	USE.—
16	(1) Coverage.—
17	(A) In General.—Section 1861(s)(2) of
18	the Social Security Act (42 U.S.C.
19	1395x(s)(2)), as amended by section $401(a)(1)$,
20	is amended—
21	(i) in subparagraph (AA), by striking
22	"and" after the semicolon at the end;
23	
ر_	(ii) in subparagraph (BB), by adding

1	(iii) by adding at the end the fol-
2	lowing new subparagraph:
3	"(CC) counseling and pharmacotherapy for ces-
4	sation of tobacco use (as defined in subsection
5	(ddd)(1));".
6	(B) Conforming amendments.—Clauses
7	(i) and (ii) of section 1861(s)(2)(K) of the So-
8	cial Security Act (42 U.S.C. 1395x(s)(2)(K)),
9	as amended by section 401(a)(2)(B), are each
10	amended by striking "and (ccc)" and inserting
11	"(cec), and (ddd)".
12	(2) Services described.—Section 1861 of
13	the Social Security Act (42 U.S.C. 1395x), as
14	amended by section 401(b), is amended by adding at
15	the end the following new subsection:
16	"Counseling and Pharmacotherapy for Cessation of
17	Tobacco Use
18	"(ddd)(1) Subject to paragraphs (2) and (3), the
19	term 'counseling and pharmacotherapy for cessation of to-
20	bacco use' means diagnostic, therapy, and counseling serv-
21	ices and pharmacotherapy (including the coverage of pre-
22	scription and nonprescription tobacco cessation agents ap-
23	proved by the Food and Drug Administration) for ces-
24	sation of tobacco use for individuals who use tobacco prod-

1	ucts or who are being treated for tobacco use which are
2	furnished—
3	"(A) by or under the supervision of a physician;
4	or
5	"(B) by any other health care professional
6	who—
7	"(i) is legally authorized to furnish
8	such services under State law (or the State
9	regulatory mechanism provided by State
10	law) of the State in which the services are
11	furnished; and
12	"(ii) is authorized to receive payment
13	for other services under this title or is des-
14	ignated by the Secretary for this purpose.
15	"(2) Such term is limited to—
16	"(A) services recommended in 'Treating To-
17	bacco Use and Dependence: A Clinical Practice
18	Guideline', published by the Public Health Service in
19	June 2000, or any subsequent modification of such
20	Guideline; and
21	"(B) such other services that the Secretary rec-
22	ognizes to be effective.
23	"(3) Each individual who is described in paragraph
24	(1) and enrolled under part B shall be eligible for the serv-

1	ices described in this subsection for up to 3 attempts to
2	cease the use of tobacco.".
3	(3) Payment and elimination of cost-
4	SHARING.—
5	(A) PAYMENT AND ELIMINATION OF COIN-
6	Surance.—Section 1833(a)(1) of the Social
7	Security Act (42 U.S.C. 1395l(a)(1)), as
8	amended by section 401(c)(1), is amended—
9	(i) in subparagraph (N), by striking
10	"or" before "substance abuse" and by in-
11	serting after "(ccc)" the following: "or
12	counseling and pharmacotherapy for ces-
13	sation of tobacco use (as defined in section
14	1861(ddd))"; and
15	(ii) in subparagraph (W), by inserting
16	"and counseling and pharmacotherapy for
17	cessation of tobacco use (as defined in sec-
18	tion 1861(ddd))" after "1861(ccc))".
19	(B) Payment under physician fee
20	SCHEDULE.—Section 1848(j)(3) of the Social
21	Security Act (42 U.S.C. $1395w-4(j)(3)$), as
22	amended by section 401(c)(2), is amended by
23	inserting "(2)(CC) (with separate payment
24	amounts for pharmacotherapy, including pre-
25	scription and nonprescription tobacco cessation

1	agents approved by the Food and Drug Admin-
2	istration)," after "(2)(BB),".
3	(C) Elimination of coinsurance in
4	OUTPATIENT HOSPITAL SETTINGS.—
5	(i) EXCLUSION FROM OPD FEE
6	SCHEDULE.—Section 1833(t)(1)(B)(iv) of
7	the Social Security Act (42 U.S.C.
8	1395l(t)(1)(B)(iv)), as amended by section
9	401(c)(3)(A), is amended by striking "or"
10	before "screenings" and inserting after
11	"1861(ccc))" the following: "or counseling
12	and pharmacotherapy for cessation of to-
13	bacco use (as defined in section
14	1861(ddd))".
15	(ii) Conforming amendment.—Sec-
16	tion 1833(a)(2)(H) of the Social Security
17	Act $(42 \text{ U.S.C. } 1395l(a)(2)(H))$, as added
18	by section 401(c)(4), is amended by insert-
19	ing "and counseling and pharmacotherapy
20	for cessation of tobacco use (as defined in
21	section 1861(ddd))" after "1861(ccc))".
22	(D) Elimination of Deductible.—Sec-
23	tion 1833(b)(8) of the Social Security Act (42
24	U.S.C. $1395l(b)(7)$, as added by section
25	401(c)(4), is amended by inserting "or coun-

1	seling and pharmacotherapy for cessation of to-
2	bacco use (as defined in section 1861(ddd))"
3	before the period at the end.
4	(4) Application of limits on billing.—Sec-
5	tion 1842(b)(18)(C) of the Social Security Act (42
6	U.S.C. 1395u(b)(18)(C)), as amended by section
7	401(d), is amended by adding at the end the fol-
8	lowing new clause:
9	"(viii) Any individual designated by the Sec-
10	retary under section 1861(ddd)(1)(B)(ii).".
11	(5) Frequency.—Section 1862(a)(1) of the
12	Social Security Act (42 U.S.C. 1395y(a)(1)), as
13	amended by section 5112(d) of the Deficit Reduction
14	Act of 2005, is amended—
15	(A) in subparagraph (M), by striking
16	"and" after the comma at the end;
17	(B) in subparagraph (N), by striking the
18	semicolon at the end and inserting ", and"; and
19	(C) by adding at the end the following new
20	subparagraph:
21	"(O) in the case of counseling and
22	pharmacotherapy for cessation of tobacco use (as de-
23	fined in section 1861(ddd)), which is performed with
24	respect to more attempts to cease tobacco use than
25	is covered under such section;".

1	(b) Promoting Cessation of Tobacco Use
2	UNDER THE MEDICAID PROGRAM.—
3	(1) Dropping exception from medicaid
4	PRESCRIPTION DRUG COVERAGE FOR TOBACCO CES-
5	SATION MEDICATIONS.—Section 1927(d)(2) of the
6	Social Security Act (42 U.S.C. $1396r-8(d)(2)$) is
7	amended—
8	(A) by striking subparagraph (E);
9	(B) by redesignating subparagraphs (F)
10	through (J) as subparagraphs (E) through (I),
11	respectively; and
12	(C) in subparagraph (F) (as redesignated
13	by paragraph (2)), by inserting before the pe-
14	riod at the end the following: ", except agents
15	approved by the Food and Drug Administration
16	for purposes of promoting, and when used to
17	promote, tobacco cessation".
18	(2) Requiring coverage of tobacco ces-
19	SATION COUNSELING AND PHARMACOTHERAPY
20	SERVICES FOR PREGNANT WOMEN.—Section
21	1905(a)(4) of the Social Security Act (42 U.S.C.
22	1396d(a)(4)) is amended—
23	(A) by striking "and" before "(C)"; and
24	(B) by inserting before the semicolon at
25	the end the following: "; and (D) counseling

- and pharmacotherapy for cessation of tobacco use (as defined in section 1861(ddd)) for pregnant women".
- 4 (3) Removal of Cost-Sharing for Tobacco 5 CESSATION COUNSELING AND PHARMACOTHERAPY 6 SERVICES FOR PREGNANT WOMEN.—Section 1916 of 7 the Social Security Act (42 U.S.C. 13960) is amend-8 ed in each of subsections (a)(2)(B) and (b)(2)(B), by inserting ", and counseling for cessation of to-9 10 bacco use (as defined in section 1861(ddd))" after 11 "complicate the pregnancy".
- 12 (c) COVERAGE UNDER FEHBP.—The last sentence 13 of section 8904(a) of title 5, United States Code, is 14 amended by striking "both for costs associated with care 15 in a general hospital and for other health services of a 16 catastrophic nature" and inserting "for costs associated 17 with care in a general hospital, for other health services 18 of a catastrophic nature, and for counseling and 19 pharmacotherapy for cessation of tobacco use (as defined 20 in section 1861(ddd)(1) of the Social Security Act)".
- 21 (d) Effective Date.—The amendments made by 22 this section shall apply to services furnished on and after 23 January 1, 2007.

1	SEC. 403. RECOGNITION OF SCHOOL-BASED HEALTH CEN-
2	TERS AS MODEL FOR DELIVERY OF PRIMARY
3	CARE FOR CHILDREN UNDER MEDICAID AND
4	THE STATE CHILDREN'S HEALTH INSURANCE
5	PROGRAM.
6	(a) In General.—Title XIX of the Social Security
7	Act (42 U.S.C. 1396 et seq.) is amended by inserting after
8	section 1911 the following:
9	"SCHOOL-BASED HEALTH CENTERS
10	"Sec. 1911A. Not later than 12 months after the
11	date of enactment of this section, the Secretary shall es-
12	tablish procedures to encourage a State program estab-
13	lished under this title, title XXI, or both, to recognize
14	school-based health centers as a model of delivery for pri-
15	mary care for children who are eligible for medical assist-
16	ance under this title or child health assistance under title
17	XXI. Such procedures shall include the following:
18	"(1) Recognition of, and reimbursement
19	FOR, SERVICES PROVIDED THROUGH SCHOOL-BASED
20	HEALTH CENTERS.—Procedures that encourage a
21	State to recognize as primary care providers under
22	this title and title XXI, providers who furnish phys-
23	ical or mental health services that are available as
24	medical assistance under this title or child health as-
25	sistance under title XXI to children who are eligible
26	for such assistance through school-based health cen-

- ters, and to reimburse such providers or centers (as appropriate) for furnishing such services to such children.
 - "(2) EXCEPTIONS TO THE 'FREE CARE'
 RULE.—Procedures that allow a State the option to
 permit school-based health centers to bill the State
 for physical or mental health services that are available as medical assistance under this title or child
 health assistance under title XXI and that are furnished to children who are eligible for such assistance through such centers without billing all children who are provided such services.
 - "(3) Exceptions to the 'third party li-ABILITY' COST AVOIDANCE POLICY.—Procedures that encourage a State to include physical or mental health services that are available as medical assistance under this title and that are provided through school-based health centers in the list of diagnosis billing codes for preventive pediatric care services that the State will pay for under this title and then seek reimbursement from any liable third party in accordance with the requirements of section 1902(a)(25).
- 24 "(4) Assurance of payment for services
 25 Covered by a contract with a managed care

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ENTITY.—Procedures that encourage a State to in-1 2 clude in any contract entered into with a managed 3 care entity (as defined in section 1932(a)(1)(B)) under this title or title XXI provisions which ensure 5 that the entity will make prompt payment to a 6 school-based health center for furnishing physical or 7 mental health services to a child who is eligible for 8 medical assistance under this title or child health as-9 sistance under title XXI that are within the scope of 10 items and services for which benefits are available 11 with respect to the child under the contract between 12 the entity and the State (or to a provider who fur-13 nishes such services to such a child through a 14 school-based health center), regardless of whether the center (or provider) is a participating provider 15 16 with respect to such entity, at a rate established by 17 the entity for such services that is not less than the 18 level and amount of payment which the entity would 19 make for the services if the services were furnished 20 by a participating provider.".

21 (b) Report to Congress.—Not later than 36 22 months after the date of enactment of this section, the 23 Secretary of Health and Human Services shall submit a 24 report to Congress on the effectiveness of the procedures 25 established in accordance with section 1911A of the Social

- 1 Security Act (as added by subsection (a)) in encouraging
- 2 the use of school-based health centers for the delivery of
- 3 primary care physical and mental health services to chil-
- 4 dren who are eligible for medical assistance under title
- 5 XIX of the Social Security Act (42 U.S.C. 1396 et seq.)
- 6 or child health assistance under title XXI of such Act (42)
- 7 U.S.C. 1397aa et seq.), together with such recommenda-
- 8 tions for administrative or legislative action as the Sec-
- 9 retary determines to be appropriate.

10 SEC. 404. PREVENTIVE HEALTH CARE DEMONSTRATION

- 11 **PROGRAM.**
- 12 (a) Establishment.—
- 13 (1) IN GENERAL.—Not later than 18 months
- after the date of enactment of this Act, the Sec-
- 15 retary of Health and Human Services (in this sec-
- tion referred to as the "Secretary") shall conduct a
- 5-year demonstration program under part B of title
- 18 XVIII of the Social Security Act under which the
- 19 Secretary establishes demonstration projects to con-
- tract with appropriate entities to provide preventive
- 21 health care to eligible beneficiaries through the de-
- velopment and implementation of a disease preven-
- 23 tion plan (as described in subsection (b)).

1	(2) Sites.—The Secretary shall designate at
2	least 2 sites at which to conduct the demonstration
3	program under this section, of which—
4	(A) 1 shall be in an urban area; and
5	(B) 1 shall be in a rural area.
6	(3) Number of eligible beneficiaries.—
7	Each demonstration project site under this section
8	shall consist of at least 1,000 eligible beneficiaries
9	representative of the population of individuals enti-
10	tled to benefits under part A of title XVIII of the
11	Social Security Act, and enrolled under part B of
12	such title. The Secretary may expand the population
13	as needed to measure statistical significance.
14	(4) Identifying eligible beneficiaries.—
15	The Secretary shall develop a method for identifying
16	eligible beneficiaries who may benefit from the dem-
17	onstration program and communicate with them re-
18	garding their eligibility.
19	(5) Voluntary Participation.—Participation
20	of health care providers, and individual beneficiaries,
21	in the demonstration program shall be voluntary.
22	(b) DISEASE PREVENTION PLAN.—
23	(1) In general.—The disease prevention plan
24	described in this subsection is a plan, developed in
25	consultation with an eligible beneficiary participating

1	in the demonstration program, to mitigate the risk
2	factors associated with a particular disease.
3	(2) Plan contents.—The disease prevention
4	plan should include the following:
5	(A) Point of contact.—The disease pre-
6	vention plan shall provide for a point of contact
7	responsible for communicating with the partici-
8	pating beneficiary and with other health care
9	providers on behalf of such beneficiary.
10	(B) Personal Health Care.—The dis-
11	ease prevention plan shall provide for instruc-
12	tion on personal health care.
13	(C) Physician and health care pro-
14	VIDER TRAINING.—The disease prevention plan
15	shall provide for the training of physicians or
16	other health care providers in the communica-
17	tion of relevant clinical information.
18	(D) Monitoring technology.—The dis-
19	ease prevention plan may provide for necessary
20	monitoring technology to facilitate the exchange
21	of information, including information such as
22	vital signs, symptoms, and health self assess-
23	ments.
24	(c) Program Standards and Criteria.—The Sec-
25	retary shall establish performance standards for the dem-

1	onstration program under this section, including best
2	practices for the prevention of chronic diseases. Such prac-
3	tices shall be standardized to the greatest extent possible.
4	The eligibility of entities or individuals to enter into a con-
5	tract to provide preventive health care under the dem-
6	onstration program shall be conditioned, at a minimum,
7	on performance that meets or exceeds such standards.
8	(d) PAYMENT.—The Secretary shall develop a meth-
9	od and level of payment for entities that participate in
10	the program under this section based on best practices,
11	as determined by the Secretary.
12	(e) WAIVER AUTHORITY.—The Secretary may waive
13	such requirements of titles XI and XVIII of the Social
14	Security Act as may be necessary to carry out the pur-
15	poses of the demonstration program under this section.
16	(f) Evaluation and Report.—
17	(1) EVALUATION.—The Secretary shall conduct
18	evaluations of—
19	(A) the benefits due to a reduction, if any,
20	in disease incidence for participants in the dem-
21	onstration projects compared to the medicare
22	population as a whole, as determined by the use
23	of appropriate statistical techniques;
24	(B) the long term cost effectiveness of the
25	demonstration projects to the medicare program

1	in terms of acute care costs avoided due to dis-							
2	ease prevention; and							
3	(C) patient satisfaction under the dem-							
4	onstration projects.							
5	(2) Report.—Not later than 6 months after							
6	the date on which the demonstration program under							
7	this section ends, the Secretary shall prepare and							
8	submit to Congress a report on the demonstration							
9	program together with—							
10	(A) recommendations on whether the dem-							
11	onstration program should be expanded in							
12	terms of its success in disease prevention and							
13	the cost effectiveness of the demonstration pro-							
14	gram; and							
15	(B) such recommendations for legislation							
16	or administrative action as the Secretary deter-							
17	mines appropriate.							
18	(g) Funding.—The Secretary shall provide for the							
19	transfer from the Federal Supplementary Medical Insur-							
20	ance Trust Fund under section 1841 of the Social Secu-							
21	rity Act (42 U.S.C. 1395t) of such funds, not to exceed							
22	\$50,000,000, as are necessary for the costs of carrying							
23	out the demonstration program under this Act.							
24	(h) DEFINITIONS—In this section:							

1	(1) APPROPRIATE ENTITY.—The term "appro-							
2	priate entity" means—							
3	(A) a chronic care improvement program;							
4	(B) a hospital; and							
5	(C) any other entity that the Secretary de-							
6	termines appropriate based on clinical, finan							
7	cial, or other requirements appropriate to carr							
8	out the purposes of the demonstration program							
9	under this section.							
10	(2) Eligible Beneficiary.—The term "eligi-							
11	ble beneficiary" means an individual who—							
12	(A) is entitled to benefits under part A of							
13	title XVIII of the Social Security Act or en-							
14	rolled under part B of such title; and							
15	(B) has 2 or more risk factors associated							
16	with—							
17	(i) chronic obstructive pulmonary dis-							
18	ease;							
19	(ii) diabetes; or							
20	(iii) any other chronic condition that							
21	the Secretary determines would be appro-							
22	priate for the purpose of providing signifi-							
23	cant potential cost benefits to the medicare							
24	program through the prevention of such							
25	condition.							

1	SEC. 405. PREVENTIVE HEALTH SERVICES FOR WOMEN.						
2	Section 1509 of the Public Health Service Act (42						
3	U.S.C. 300n-4a) is amended to read as follows:						
4	"SEC. 1509. ESTABLISHMENT OF PROGRAM FOR ADDI						
5	TIONAL PREVENTIVE HEALTH SERVICES.						
6	"(a) In General.—The Secretary, acting through						
7	the Director of the Centers for Disease Control and Pre-						
8	vention, may, through a competitive review process, award						
9	grants to States that have received grants under section						
10	1501 for a fiscal year, to enable such State to carry our						
11	programs—						
12	"(1) to provide preventive health services, in ad-						
13	dition to the services authorized in such section						
14	1501, for diseases such as cardiovascular diseases,						
15	osteoporosis, and obesity;						
16	"(2) to provide screenings, such as screening						
17	for blood pressure, cholesterol, and osteoporosis, and						
18	other services that the Secretary, acting through the						
19	Director of the Centers for Disease Control and Pre-						
20	vention, determines to be appropriate and feasible;						
21	"(3) for health education, counseling, and inter-						
22	ventions for behavioral risk factors, such as physical						
23	inactivity and poor nutrition, and diseases referred						
24	to in paragraph (1);						
25	"(4) to provide appropriate referrals for medical						
26	treatment of women receiving services pursuant to						

1	paragraph (1) through (3), and ensuring, to the ex-						
2	tent practicable, the provision of appropriate follow-						
3	up services; and						
4	"(5) to evaluate the activities conducted under						
5	paragraphs (1) through (4) through appropriate sur-						
6	veillance, research, or program monitoring activities.						
7	"(b) Status as Participant in Program Regard-						
8	ING BREAST AND CERVICAL CANCER.—The Secretary						
9	may not make a grant to a State under subsection (a)						
10	unless the State involved agrees that services under the						
11	grant will be provided in conjunction with entities that are						
12	screening women for breast or cervical cancer pursuant						
13	to a grant under section 1501.						
14	"(c) Applicability of Provisions.—The provi-						
15	sions of this title shall apply to a grant under subsection						
16	(a) to the same extent and in the same manner as such						
17	provisions apply to a grant under section 1501.						
18	"(d) Funding.—						
19	"(1) In general.—There is authorized to be						
20	appropriated such sums as may be necessary to						
21	carry out this section for fiscal year 2007 and for						
22	each subsequent fiscal year.						
23	"(2) Limitation regarding funding with						

RESPECT TO BREAST AND CERVICAL CANCER.—No

additional resources shall be appropriated for a fis-

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1	cal year under paragraph (1) unless the amount ap-							
2	propriated under section 1510(a) for such fiscal year							
3	is at least \$173,920,000.".							
4	TITLE V—HELP (HEALTHY LIFE-							
5	STYLES AND PREVENTION)							
6	AMERICA TRUST FUND							
7	SEC. 501. HELP (HEALTHY LIFESTYLES AND PREVENTION)							
8	AMERICA TRUST FUND.							
9	(a) Creation of Trust Fund.—There is estab-							
10	lished in the Treasury of the United States a trust fund							
11	to be known as the "HeLP (Healthy Lifestyles and Pre-							
12	vention) America Trust Fund" (referred to in this section							
13	as the "Trust Fund"), consisting of such amounts as may							
14	be appropriated or credited to the Trust Fund as provided							
15	in this section.							
16	(b) Transfers to Trust Fund.—There is hereby							
17	appropriated to the Trust Fund an amount equivalent							
18	to—							
19	(1) the increase in revenues received in the							
20	Treasury as the result of the amendment made by							
21	section 304 of this Act,							
22	(2) the increase in revenues received in the							
23	Treasury as the result of the amendments made by							
24	title II of this Act, and							

1	(3) the receipts paid by tobacco companies
2	under subtitle B of title III of this Act.
3	(c) Distribution of Amounts in Trust Fund.—
4	(1) Mandatory expenditures.—On a fiscal
5	year basis (beginning with fiscal year 2007) and
6	without further appropriation the Secretary of the
7	Treasury shall distribute from amounts in the Trust
8	Fund such amounts as are necessary to provide for
9	the Federal expenditures attributable to the fol-
10	lowing:
11	(A) The amendments made to the Fruit
12	and Vegetable Program by section 101 of this
13	Act.
14	(B) Smoking cessation drugs under title
15	XIX of the Social Security Act as identified by
16	the Secretary of Health and Human Services.
17	(C) Coverage of smoking cessation under
18	the Federal Employee Health Benefits Program
19	under chapter 89 of title 5, United States Code
20	(as amended by section 402(c)).
21	(D) The amendments made to the medi-
22	care program under title XVIII of the Social
23	Security Act by sections 401 and 402 of this
24	Act.

1	(E) The preventive health care demonstra-
2	tion program carried out under section 404 of
3	this Act.
4	Such amounts shall be in addition to any other
5	amounts appropriated for such purposes.
6	(2) Discretionary expenditures.—Amounts
7	in the Trust Fund not to exceed \$2,050,000,000
8	shall be available, as provided in appropriation Acts,
9	for each fiscal year (beginning with fiscal year 2007)
10	only for purposes of making expenditures to carry
11	out the following:
12	(A) School nutrition environment enhance-
13	ment grants under section 18(l) of the Richard
14	B. Russell National School Lunch Act (as
15	added by section 103).
16	(B) Community grants to prevent and re-
17	duce the incidence of chronic disease under sec-
18	tion 399P of the Public Health Service Act (as
19	added by section 211).
20	(C) The preventive medicine and public
21	health training grant program carried out
22	under section 747A of the Public Health Serv-
23	ice Act (as added by section 212).
24	(D) Federal-State tobacco counter-adver-
25	tising programs under section 399Q of the Pub-

1	lic Health Service Act (as added by section
2	305).
3	(E) Preventive health services for women,
4	including well-integrated screening and evalua-
5	tion for women across the Nation, under section
6	1509 of the Public Health Service Act (as
7	added by section 405).
8	(F) Carol M. White Physical Education
9	Program under subpart 10 of part D of title V
10	of the Elementary and Secondary Education
11	Act of 1965.
12	(G) Research regarding obesity under sec-
13	tion 601 of this Act.
14	(H) Expanded Food and Nutrition Edu-
15	cation Program under section 3175 of title 23,
16	United States Code.
17	(I) The following programs under the au-
18	thority of the Secretary of Health and Human
19	Services through the Centers for Disease Con-
20	trol and Prevention:
21	(i) Nutrition and physical activity
22	grants.
23	(ii) Division of Adolescent and School
24	Health.
25	(iii) Verb Campaign.

1	(iv) Prevention research centers.							
2	(v) 5-a-day programs.							
3	(vi) Steps to a healthier United							
4	States.							
5	(J) Access to local foods and school gar-							
6	dens, as authorized by section 122 of the Child							
7	Nutrition and WIC Reauthorization Act of							
8	2004 (Public Law 108–265).							
9	(d) Application of Certain Rules.—For pur-							
10	poses of this section, rules similar to the rules of sections							
11	9601 and 9602 of the Internal Revenue Code of 1986 shall							
12	apply.							
13	TITLE VI—RESEARCH							
14	SEC. 601. EXPANSION OF RESEARCH REGARDING OBESITY.							
15	The Secretary of Health and Human Services shall,							
15 16	The Secretary of Health and Human Services shall, based on the conclusions of the United States Preventive							
16	·							
16 17	based on the conclusions of the United States Preventive							
16 17	based on the conclusions of the United States Preventive Services Task Force on Obesity, conduct research on obe-							
16 17 18	based on the conclusions of the United States Preventive Services Task Force on Obesity, conduct research on obe- sity prevention, treatment, and control with regard to the							
16 17 18 19	based on the conclusions of the United States Preventive Services Task Force on Obesity, conduct research on obesity prevention, treatment, and control with regard to the following:							
16 17 18 19 20	based on the conclusions of the United States Preventive Services Task Force on Obesity, conduct research on obesity prevention, treatment, and control with regard to the following: (1) The effectiveness of physical activity and di-							

(2)	The	cost-effe	ectiveness	of in	ntensive	dietary
and p	phys	sical	activity	counselin	g to	prevent	, treat,
and c	onti	rol ob	esity in	a variety	of po	pulations	S.

- (3) The effectiveness of dietary and physical activity counseling among children and adolescents, low income populations, and minority groups in the primary care setting to prevent, treat, and control obesity.
- (4) The effectiveness of the assessment of obesity by a primary care physician and subsequent referral for obesity counseling to a nonaffiliated obesity expert or specialist.

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